UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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UNITED STATES OF AMERICA,

v. 19 Cr. 285 (GBD)

LAURENCE F. DOUD III,

Defendant.

Trial

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New York, N.Y.
January 18, 2022
9:30 a.m.

Before:

HON. GEORGE B. DANIELS,

District Judge
-and a Jury-

APPEARANCES

DAMIAN WILLIAMS
United States Attorney for the
Southern District of New York
BY: NICOLAS T. ROOS
ALEXANDRA ROTHMAN
THOMAS S. BURNETT
Assistant United States Attorneys

ROBERT C. GOTTLIEB
DERRELLE M. JANEY
PAUL R. TOWNSEND
Attorneys for Defendant

Also Present: Sunny Drescher
Jacqueline Hauck
Paralegal Specialists
Special Agent George Burdzy, DEA
Investigator Kathleen Whitmore, DEA

(In open court; jury not present)

THE DEPUTY CLERK: 19 CR 285, United States v. Laurence F. Doud III.

MR. ROOS: Good morning. For the government, Nicolas Roos, Alexandra Rothman, and Thomas Burnett.

MR. GOTTLIEB: Good morning. Robert C. Gottlieb & Associates by Robert Gottlieb for Mr. Doud.

MR. JANEY: Also for Mr. Doud, the Janey Law Firm by Derrelle Janey.

MR. TOWNSEND: And Paul Townsend.

THE COURT: Three things that we'll address right now while we're waiting for jurors. One, I understand the defense would like a room that they can use. What I think I may do is I'm going to give the witness room to the government, since they'll be bringing in their witnesses. I will give you the attached jury room to this courtroom, which is a smaller jury room than what we're using, so you can utilize that.

MR. GOTTLIEB: Thank you.

THE COURT: And we'll lock it up if need be.

I know there is an issue with regard to Paulsen and Castro that the parties wanted to address. And one other issue. We have four jurors so far. I have a letter if the defense still thinks this is a relevant consideration. I have a letter from the jury department with regard to the breakdown in the numbers of the jurors. I will give you both sides a

copy of that letter. I'll give it to you now.

MR. GOTTLIEB: Thank you.

THE COURT: You're welcome. We have two jurors who raised issues with regard to timing. One raised an issue last week which I think I communicated to the parties, Juror No. 8 who says she has -- I think she is the film producer or something. She says she has some event the 24th and the 28th. Now we've gotten some indication this morning from I believe Juror No. 6 who says that he has a, I believe a son or a daughter who is graduating from basic training on February 4. That's the only information that I have.

As you remember, we do have 17, we need to go down to 16. So, we can either excuse one or both of them or not. Quite frankly, I don't think that either one of their reasons are particularly compelling at this point, given that they've been chosen as jurors, but since we do have to get rid of one person, I'm willing to be a little bit more flexible and take direction from the parties on this issue. But as soon as we swear in these 16 jurors, or 15 or 16 jurors, I'm going to let them know clearly we're not going to hear any more excuses.

You can tell me what your position is, if you have one now, with regard to the juror who says she has some job related thing I guess it would be next Monday and next Friday. Some kind of a press event with regard to her job. And Juror No. 6, he says, it's only been communicated to me so far that this

event is on February 4., which is a Friday. I don't know if that means he needs travel time if we can accommodate him.

My inclination would be is to maybe, if we're going to accommodate either one of them, rather than telling them it's just too bad they have to be here, is excuse the one who has the two day event starting next week. And considering keeping the other person, and as we get closer, I'll hear your suggestions, but my first reaction would be is that I would be willing to keep him until we get closer, and then as we get close, if the parties agree to go ahead and excuse him prior to February 4, or to take February 4 off if it's only that day that we need.

But, I can bring them in here and we can get some more information, but why don't I get a reaction first. What's the government's position?

MR. ROOS: Well, on the first juror, the one with the press conference or whatever it is that your Honor's chambers informed us of last week. Our view is that, at least based on the information we have right now, that it's not a basis to excuse her. We should just keep her on the jury.

I talked briefly with Mr. Gottlieb, I think that's his view unless it's changed.

As to the other one, I think there is a possibility, frankly, we are not even still going on February 4 or I think maybe you would give a Friday off or something. My initial

reaction is just leave both of them on for now.

THE COURT: The only thing is if we leave both of them on for now we'll still have to excuse a juror. So, it didn't make a whole lot of sense to excuse another juror who has got no problem and then keep two jurors that do have a problem. That's my only reaction to that. But I'm willing to accommodate the parties if that's what you prefer to do. We're going to have to get rid of somebody today.

MR. ROOS: I guess not everyone is in yet.

THE COURT: Say it again?

MR. ROOS: Not everyone is in yet.

THE COURT: Not everyone is in. It could be someone else who has a problem too.

MR. ROOS: If we are going to excuse someone and your Honor is inclined to excuse one of them, I guess maybe it would be appropriate to do some further followup to understand, is she being told by her employer this is something she has to do or is it necessary for her own income, questions like that just to get a better sense. Same with the gentleman. Does he need to travel for this or is it just one day off?

THE COURT: Mr. Gottlieb, what's your reaction?

MR. GOTTLIEB: My reaction, your Honor, it may surprise you, I'm actually in agreement with the government at least this morning. And I think at this point, everyone worked very hard to select the jurors. I don't believe it rises to

the level to excuse them at this point. Those are the types of excuses that oftentimes your Honor learns that, within a day, if they're told you have to be here, they manage somehow to rearrange their schedule.

So, I would ask that we proceed with the plan that we discussed last week when we selected the jurors. And I know we have one extra in case something happened today where we had to fill a seat. If that doesn't occur, the two jurors who have raised questions, I don't believe there is reason to excuse them.

THE COURT: You think we should go ahead and excuse the last alternate and keep these two?

MR. GOTTLIEB: Correct, your Honor.

THE COURT: All right. Well, why don't I do this. Let's see if one or both of them have arrived already. I'll bring them each up and tell them, I'll hear what they have to say, but we'll send it back to the jury room. Let's see where we are after we talk to them. I still feel it is a little awkward to sort of say to them they should stay and excuse someone who hasn't complained about it. It sends the wrong signal than I want to send.

I agree with you, I don't think at this point, and, clearly, if there was a need for these jurors to stay here, what we've been told and the timing which we've been told about this, is not a compelling reason at this point to make their

personal and professional business a priority over this jury trial. But let me see who is here, check and see if one or both of those are here.

I understand defense wanted to be heard further with regard to this Paulsen and Castro application.

MR. JANEY: Yes, good morning, your Honor.

THE COURT: Good morning.

MR. JANEY: I'm not sure if the Court has received any type of letter of correction, I know the defense has not, pertaining to the government's submission dated the 13th. But we felt it important before the decision is made, your Honor, to raise with the Court late Sunday night as well as late last night we received additional 3500 material that bears on this issue, and I think demonstrates some of the statements that were made in the government's submission are simply factually inaccurate.

More particularly, your Honor, as it pertains to Barbara Castro, the government's submission, in particular page two of the submission, indicates that, number one, Barbara Castro bought her drugs from Old Town Pharmacy. And she in her 3500 material produced late last night or Sunday night, I forget which, the hours are drawing close together. But, she indicates in the 3500 material, your Honor, that she bought her drugs from several -- one, two, three, four different pharmacies, in addition to Old Town.

The most that she can testify about, based on the 3500 material, your Honor, is that maybe she bought most of her narcotics from Old Town. And as to the government's statement in its submission on page two that she also bought her drugs from another RDC customer indicated as New Dorp, she indicates in the 3500 material that she can't even recall New Dorp Pharmacy. So, your Honor, that's important. Because it puts a different perspective on the government's offer of proof.

Further, your Honor, an additional 3500 material from another witness, I believe it's the H.D. Smith witness, and this goes to the issue as to whether RDC was the exclusive supplier of oxycodone to Old Town. There, this witness indicates that H.D. Smith sold these narcotics, certainly through September of 2015, but indicates it may have continued to sell them after September. She doesn't know what the sales were after September.

For the purposes of the record, your Honor, and for the government's perspective, I'm referring to 3500 material Bates stamped at the first document 3523-039. And the Barbara Castro related 3500 material at 3552-175.

So, your Honor, you have our submission in response to the government's document that we filed before noon on Sunday. I don't have to repeat our statements there, your Honor. But certainly, as we say in those papers, and certainly in concert with the 3500 material that we received late Sunday night and

late last night, the government continues to strain, to strain to demonstrate the relevance of Barbara Castro as a witness in this case, strains to demonstrate that it's probative in any way, that it's not misleading, that it doesn't create unfair prejudice for the jury and for this defendant.

Based on this 3500 material, your Honor, in addition to the case law that we explicated in our submission, that relevance certainly isn't there, it's not probative, the witness cannot testify to all of the statements that the government indicates in its submission by way of its offer of proof. Thank you, your Honor.

THE COURT: The government want to be heard further?

MR. ROOS: Yes, your Honor. A few things. So, for starters, I think there are some factual inaccuracies in the defense submission.

Let me just lay out for the Court the connection to Barbara Castro. There is going to be evidence in the case that RDC was a supplier of Old Town Pharmacy for several years, the entirety of the conspiracy period, 2013 to 2017. The ARCOS data, which is the data that distributors, so Rochester Drug and other --

THE COURT: Close the door, please.

MR. ROOS: Rochester Drug and other companies submit to the DEA, that indicates who is supplying which pharmacy.

So the defense submission is inaccurate when saying we

don't know if a criminal enterprise like Old Town is correctly reporting things. It is not Old Town that's doing the reporting; it is the distributor. According to all of the data that the DEA has regarding distributors, it shows who is selling to which stores when.

So we look at that data, and we see, as the 3500 for the H.D. Smith witnesses, H.D. Smith did sell to Old Town as did RDC up to 2015. But from the end of 2015 to the end of the conspiracy period, there is one supplier for Old Town, and that is RDC.

Now, during that period, during the entirety of that period, but in particular when RDC is the sole supplier, Barbara Castro goes to Old Town Pharmacy. The only pills she is getting are the ones that are supplied by RDC.

Why is her testimony relevant? She will establish two important parts of the case: Number one, that the prescriptions she was getting were not medically necessary from Dr. Anderson. That's probative because Dr. Anderson shows up all over the RDC files. We'll see that in e-mail records and dispensing records. And second, she will set forth evidence that Old Town was distributing not just to her, but to other people she observed there, who did not need prescriptions, those were not medically necessary prescriptions.

THE COURT: I'm not sure how she can testify to that.

MR. ROOS: She can certainly testify to her own

prescription.

THE COURT: How can she testify whether or not other people sitting in the waiting room had a valid prescription?

MR. ROOS: She can't testify definitively. I'll give that to your Honor. Certainly she can testify about her observations, from which there is relevant evidence from which the jury can conclude there were other people diverting their pills. What will she say? She'll say she saw the same people going to Dr. Anderson at 2 in the morning to get pills, paying cash, and the next morning she'd see them at Old Town filling their prescriptions. She'll say some of those people looked like they were 18 and 19 years old and looked to be healthy. Some appeared to be junkies.

From that, that's first-hand direct evidence relating to the fact that Old Town was diverting its pills.

THE COURT: The part that you describe as her opinion about whether or not they were drug users or they appeared to be healthy or sick. It doesn't seem she's particularly qualified to give that kind of opinion.

MR. ROOS: A person walking down the street could say that their observation is somebody looks like they are high or they have track marks or something like that.

THE COURT: Yeah, but you don't necessarily manifest. If you have a prescription for oxycodone, I couldn't tell you if there is a person in this room who does not have a

prescription for oxycodone and is not presently on oxycodone. How would I know that? I'm not qualified to tell that.

If somebody is sleeping or somebody's talking or someone's just observing, I don't see how she is qualified to describe somebody as somebody, one, who is on drugs, or two, who doesn't genuinely need that drug, or three, can say that that drug was dispensed to them illegally.

Maybe there's circumstantial evidence, as you say. She can testify as to what appears her observations were, who was in the room and that she saw the same people the next day. But her opinions and conclusions about that, I don't think that she's competent, that's competent evidence for the jury to accept.

MR. ROOS: That's fair, your Honor. I think still it is highly relevant that she herself was diverting pills. There is other people she knows first-hand. Her brother is going to the exact same doctor and the same pharmacy. She'll testify he was diverting. She can name other people who were to Old Town doing the same thing. There she has first-hand knowledge. It is not just opinion testimony.

THE COURT: How does she have first-hand knowledge?

MR. ROOS: Other people she was swapping pills with and things like that. There is a group of them, four, five, six people, all of whom would be getting max prescriptions, then going, filling them, trading pills.

THE COURT: I'm not sure the extent of the testimony that you want from her. There are a couple of things that concern me. I don't find compelling the argument that this is or isn't the only pharmacy where she was getting pills. The question is, is this one of the pharmacies that she was getting the pills, and if the pills that she was getting from this pharmacy are pills that were distributed by RDC, that seems to be sufficient connection with RDC. Whether or not she's getting pills also from some other place, quite frankly, I'm not sure it's relevant one way or the other. As long as it's established that she is being given pills that RDC distributed through this pharmacy. And I think that is sufficient connection.

Yes, sir.

MR. JANEY: Your Honor, the reason that we raise it is because, as I understood it, your Honor put to the government as its offer of proof to show the direct connection both with respect to Castro and with respect to Paulsen.

THE COURT: Why isn't that a direct connection?

MR. JANEY: Well --

THE COURT: If RDC is the only drug distributor giving drugs to that pharmacy, and she's getting drugs from that pharmacy, she's getting RDC drugs. Isn't she?

MR. JANEY: Yes, your Honor. If that were in fact factually correct. Which I'm suggesting this morning, based on

the 3500 material, and I'm happy to offer it up to your Honor.

THE COURT: I didn't hear you describe the 3500 material as being inconsistent with that.

MR. JANEY: Let me be clearer. It is consistent with raising the question as to whether Old Town exclusively got these pills --

THE COURT: That's what I say. I understand your argument whether they exclusively got the pills.

MR. JANEY: That's the government's offer of proof in their submission to the Court.

THE COURT: I'm sorry. I'm not sure what evidence that you just articulated that you say you just got that goes to that issue of whether or not Old Town was exclusively -- that the only pills that Old Town was selling was from RDC.

MR. JANEY: The second document, your Honor, in the 3500 material that I described pertaining to Deborah Komoroski raises a question.

THE COURT: How does it raise that question?

MR. JANEY: Because she says that she doesn't recall whether H.D. Smith did or did not continue to provide the narcotics in question to Old Town Pharmacy during the time frame that the government says RDC was the exclusive provider.

THE COURT: What she remembers and what she doesn't remember does not put the truth or the lie to the testimony of someone else who says it happened.

MR. JANEY: What it does undermine, and correct, your Honor, is that the government's statement that RDC was the exclusive provider in that time frame. Her statement says otherwise.

MR. ROOS: It doesn't. It says she can't remember what happened afterwards. But we have the data. We have the data that says who was the exclusive supplier, and we have the data in Castro's 3500 that says she was filling at Old Town during that period.

MR. JANEY: In its offer of proof attached to the submission dated the 13th, the government does not attach anything, articulate anything, describe anything, with respect to this ARCOS data that would substantiate exactly what Mr. Roos just described.

THE COURT: I don't understand from what the information that you have, I don't understand how it in any way casts doubt on the fact that this pharmacy got their drugs exclusively from RDC.

MR. JANEY: Your Honor, I think that it's fair to infer from the 3500 material that the witness was asked when did you provide these drugs to Old Town.

THE COURT: Which witness?

MR. JANEY: Deborah Komoroski. And I think it's fair and reasonable to infer she is saying, in sum and substance, I know we did it through September of 2015.

THE COURT: Right.

MR. JANEY: And then, I think it's fair to infer from the 3500 material that she was asked did H.D. Smith provide it at any time thereafter, and she is saying, and I think it's fair to infer, she's saying I'm not exactly sure what happened after that, but it could have been.

THE COURT: Okay. So, she can't establish that. The fact that she can't establish that, how does that cast doubt on the records that do indicate that?

MR. JANEY: I'm not sure the government's actually produced records in its offer of proof.

THE COURT: I don't know.

MR. JANEY: But the question, the question put to the government in their burden for the purpose of the motion was, show me. Show me the information that substantiates that RDC was the exclusive provider. And what I am suggesting to the Court this morning is that the government didn't carry that burden. The government's own witnesses are saying we're not really sure.

THE COURT: One of the government's own witnesses says I'm not sure, but the records that they say that they have and they have produced to you indicate only one thing, that this was the exclusive supplier. RDC was the exclusive supplier to this pharmacy.

MR. JANEY: I'll tell you --

THE COURT: Do the records reflect that? Have you received those records?

MR. JANEY: I don't see anything in this letter from --

THE COURT: I didn't ask you about that. I am asking you, did they produce the records to you?

MR. JANEY: Yes.

THE COURT: And do the records reflect that?

MR. JANEY: What I would say is the defense, we can't discern whether RDC was the exclusive provider to Old Town Pharmacy during this time frame.

THE COURT: The question isn't whether you can discern it. The question is, is there evidence of it. And is that evidence probative to be put before the jury. And I don't hear you saying that you have any evidence to the contrary that contradicts any of the records that they say, and I don't know what testimony is going to be, but whatever testimony it's going to be that, or you attempting to dispute the fact that you have no evidence and no reason to believe that this pharmacy was receiving drugs from someone other than RDC, despite the fact that they say that that's what the records and the testimony supports.

MR. JANEY: Certainly the testimony of Barbara Castro, your Honor, based on her 3500 material submitted last night cannot be that I only bought my drugs from Old Town that was

supplied by RDC.

THE COURT: That's fine. I don't know if she --

MR. JANEY: She has no knowledge of that. She has no knowledge.

THE COURT: I agree with you. She has no knowledge of that and we discussed that even last week. That, look, she's not the person who can say where all the RDC drugs came from. So, if they can't establish that, they can't give credible evidence that the RDC drugs were given to this pharmacy, or if you have some evidence to the contrary that you, despite their evidence, that they say that they have proffered to you, and that they say will be available to present at this trial, then what you're arguing goes to its weight, not to its admissibility.

MR. JANEY: Just to further the point, your Honor, the witness cannot --

THE COURT: Which witness?

MR. JANEY: Barbara Castro. She cannot argue that she knows that all of the Old Town Pharmacy drugs that she purchased came from RDC.

THE COURT: I agree with that.

MR. JANEY: She cannot testify to that.

THE COURT: I agree with that. She has no way to know that.

MR. ROOS: She's not going to say she knows who the

supplier was.

THE COURT: Right. My position is this. That if they can establish that the drugs that she bought from this pharmacy -- she got from this pharmacy were drugs supplied by RDC, if they have credible evidence for which a jury could reasonably conclude that, then they have a basis for having her testify that she in fact did not have a medically necessary reason to get these drugs and were given these drugs, even though there were red flags that the company saw that gave them an indication that they shouldn't keep supplying these drugs. That's what the real issue comes down to. And the question really is, is there testimony specifically with regard to what evidence of red flag and diversion that the government is going to present with regard to these drugs, supplied to those pharmacies, that you say that Mr. Doud was part of the conspiracy. Is there going to be testimony that there was red flags about both of these pharmacies?

MR. ROOS: Just to give you a sense of sort of the places in the case where the testimony about Old Town Pharmacy will come in. We'll have, as you know, Barbara Castro who will testify going to Old Town Pharmacy. We'll have Jessica Pompeo who was one of the compliance analysts at Rochester Drug, she'll testify about the red flags relating to Old Town Pharmacy. And also some of the prescribers, such as Anderson and others. And then we'll have the expert David Cutler who

will testify about the data around RDC. And that's where you'll see -- around Old Town -- and that's where you'll see an analysis related to both dispensing data and the ARCOS data, which is where the facts relating to sole supplier is.

THE COURT: What do you anticipate will be the nature of the proof of Mr. Doud's participations in this conspiracy?

MR. ROOS: In Old Town?

THE COURT: In this conspiracy.

MR. ROOS: In the overall conspiracy? Throughout the case?

THE COURT: Well, related to these pharmacies.

MR. ROOS: With respect to the pharmacies, I think the proof is going to come in a few different forms. The witness testimony --

THE COURT: What is going to be the proof of his participation?

MR. ROOS: With respect to the overall scheme?

THE COURT: Yes. What role did he play?

MR. ROOS: The testimony is going to come from a few different witnesses that he directed them to not terminate and not report pharmacies, to open new pharmacies without doing due diligence. There is also e-mail evidence that will come through a summary witness that we'll see similar type communications and writing.

THE COURT: And these two pharmacies, Paulsen's

pharmacy and Castro, pharmacy that she attended, did RDC in fact have information that would have been red flags for them to either terminate, further investigate, or notify DEA?

MR. ROOS: I'm going to let my colleague speak to Paulsen Regal Remedies. But let me say on Old Town, there will be e-mails in the record where they describe not just the red flags about that pharmacy, but they even name Dr. Anderson in particular and how he's highly concerning.

THE COURT: And is this e-mails among whom?

MR. ROOS: That is amongst the compliance department.

THE COURT: Okay.

MR. ROOS: And Ms. Rothman can speak to Paulsen.

THE COURT: All right.

MS. ROTHMAN: Your Honor, Mr. Paulsen was the owner of Regal Remedies, a pharmacy in Staten Island.

THE COURT: I know that.

MS. ROTHMAN: The RDC compliance department exchanged e-mails about the red flags of diversion at Regal Remedies in 2016, during a time period when he was diverting illegal prescriptions. So I'm thinking of specifically an e-mail in which there is flags about the amount of cash, the amount of oxycodone being prescribed at that pharmacy. And yet, during the relevant time period, they didn't shut off Regal Remedies. They kept supplying oxycodone to the pharmacy.

THE COURT: You were saying he was a party to this,

these e-mails or he was the person giving them directions not to report?

MS. ROTHMAN: Who was a party to the e-mails?

THE COURT: Mr. Doud.

MS. ROTHMAN: Mr. Doud is not copied on the specific e-mails with respect to Regal Remedies, but employees in his compliance department will explain they were directed to not shut off pharmacies like Regal Remedies by Mr. Doud. That they were directed to not report pharmacies like Regal Remedies by Mr. Doud.

THE COURT: Okay. Well, my position is --

MR. GOTTLIEB: Your Honor?

THE COURT: Yes, sir.

MR. GOTTLIEB: I'm sorry. Separate and apart from the argument that you've already heard. I implore your Honor to remember what was just said by Mr. Roos and now Ms. Rothman in response to your question about what Mr. Doud's involvement was. It was -- and I wrote it down -- he told the employees not to terminate pharmacies. That's the representations the government has just made to you.

Now, thank God we have a trial. But I point that out, because going back to Castro, the real issue, your Honor, is what is the relevance. Because in the documents we received regarding their interviews, she talks about being addicted going back to '99, in the early 2000s, long before this.

So, I would ask your Honor to just clarify, so I can be sure, because I am going to be cross-examining Ms. Castro, what are the limits of the direct examination. Are they really going to be able to put this woman, who has had an unbelievably sad and tragic life, on the stand to talk about, as in her 3500 material, about all the years beginning in '99 or 2000 that she was strung out and she went to all these doctors, long before the time of this indictment, having nothing to do with buying prescription drugs from Old Town.

If she's going to be limited to what appears to be the basis for the government's request to introduce this, just to show the connection during the time of this indictment, 2012 to 2017, there was a period of time when she purchased narcotics from Old Town and then they can put all the ARCOS stuff in. If that's the limits, I just want it clarified to the extent of their testimony, which is so over the top, your Honor, quite frankly.

THE COURT: I understand your argument. I'm getting ready to address it.

MR. ROOS: Just to be clear, the 3500 is a debriefing of Castro. So there is stuff in there that I don't plan to attempt to elicit from her on the stand. A little bit of her background is relevant, just to establish that she doesn't actually need the oxycodone, that she became addicted, not that it is a pain that she needs. And the history about these other

doctors is relevant to establish she is a doctor shopper. But, first of all, no one is alleging, for instance, that one of the prior doctors, this Dr. Felix Lanting, no one is saying that that's Doud or RDC's fault or anything like that. We are going to move through it very quickly. It's just to establish she is a doctor hopper.

I'm going to in fact say to her I want to focus on the period, after a little bit of the background, I want to focus on the period of 2013 to 2016.

THE COURT: I think limited testimony from her is relevant and its probative value outweighs the potential prejudice given the issues in this case.

First of all, I think she can testify that she went to this pharmacy, and the period during the conspiracy that she obtained these prescriptions from Dr. Anderson and/or other doctors that were not medically necessary, that she went and filled those prescriptions at the pharmacy, and that there is evidence that RDC, if there is evidence to connect that RDC, they knew there were red flags here that they should have acted differently.

She can testify minimally that she, prior to this, that she had whatever condition that warranted her getting a prescription, and that she filled those prescriptions, and at a point in time she was addicted and started filling those prescriptions to satisfy her addiction, rather than for a

medically necessary condition.

Beyond that, the testimony should concentrate on the period of time of the conspiracy, and her activities in obtaining the prescription that was not medically necessary in obtaining the drugs from the pharmacy, if there is evidence to indicate that that pharmacy gave her drugs RDC drugs.

With regard to, specifically in the letter, there are certain things I will preclude. She can testify as to her observations of individuals, other individuals also there when she was there. Very limited testimony. Clearly she's not in a position to testify that there were many other customers in the pharmacy that were plainly addicted or selling the OxyContin. She has no basis to make such a statement, unless she saw somebody selling OxyContin. So there is nothing about an individual in a pharmacy that supports that conclusion. She also cannot testify that the signs of diversion were obvious to a person who simply stepped in the pharmacy.

She can testify as to what she did, what she saw. If the reasonable inference for the jury to draw is that one would have clearly known that this was being dispensed improperly, although, quite frankly, that's not really the real issue here. The real issue is whether or not, regardless of who the individuals were that were selling or buying the drugs, that the issue is whether or not Mr. Doud was part of a conspiracy in which he actively participated in directing or acting in a

manner that would defraud the DEA and/or distribute drugs that he had a good reason and knew that these drugs were not being properly dispensed.

So, I think that her limited testimony, and primarily with regard to her activities of obtaining her own prescriptions, and filling those prescriptions at the pharmacy, as long as there's a connection to the particular pharmacy, as I've indicated, that testimony is relevant.

With regard to Paulsen, I think Paulsen is pretty much the same thing. Paulsen owns the pharmacy, he knows where he got the drugs. If he says that he got drugs from RDC, and he was selling those drugs improperly and there is evidence that RDC during that period of time of the conspiracy, there is testimony and/or records that indicate that they knew or should have known this, and Mr. Doud knew or should have known this, and participated in a conspiracy to distribute those drugs, that evidence is relevant.

Although, I think neither one of these witnesses, the evidence is particularly lengthy and it needn't go significantly beyond the activities and personal observations of those witnesses.

Could we bring in Ms. Robins? 8.

I believe all our jurors are here.

MR. JANEY: If I may, while we're waiting for the juror, just an administrative question. My understanding is

that when we are in the box, that we can remove the mask.

THE COURT: That's correct. Even with the witness.

(Juror present)

THE COURT: Ms. Robin? Just take a seat in the first seat there.

JUROR NO. 8: Here?

THE COURT: Yes. My understanding is that you called last week and brought to our attention that you believe you had some conflict.

Does that still exist or and what's the nature of that?

JUROR NO. 8: Yes, it only came up on Friday. That's why I didn't know about it when I was seated as a juror.

As I had said, I'm a film producer. And we have a film opening on Friday, and the publicist resigned two weeks ago, and they've been putting together a press junket which always happens before a film, although smaller now because of COVID. And I am the one now as the producer that has to oversee it, to be with the director for two days, Monday and Tuesday of next week.

THE COURT: Monday and Tuesday of next week? And is this something they can do without you, and is there a reason that this can't be rescheduled?

JUROR NO. 8: It can't be rescheduled for sure.

THE COURT: Excuse me?

JUROR NO. 8: It cannot be rescheduled for sure. As far as doing it without me, I'm the highest person in the ranks, other than the director at this point, who has worked for him for 40 years and that's why we wants me to oversee it with him. Since the publicist who had been with him for many, many years cannot be, because she's gone.

THE COURT: All right.

JUROR NO. 8: We're on a very limited staff now, since this is a film we made three years ago, first coming out now in the United States. And because we haven't been able to make a film since then, I'm one of the few people that's been kept on employ.

THE COURT: And when did they decide that they were going to schedule this and how did it get scheduled without you?

JUROR NO. 8: They had been talking about it on and off for some time. I had -- I didn't realize that the publicist had withdrawn from the -- from working with this director.

THE COURT: Well, I'll discuss it with the lawyers. But, I can tell you that I'm not sure that we can accommodate you, now that you've already been selected as a juror.

JUROR NO. 8: Okay.

THE COURT: But I'll discuss it with them. As I say, it may be that they're just going to have to do without you at

this point given where we are, that we're ready to start this trial today. But let me speak to the lawyers and I'll get back to you in a second.

JUROR NO. 8: Okay.

THE COURT: Okay.

(Juror No. 8 not present)

(Juror No. 6 present)

THE COURT: Mr. Brown, just take a seat in the first seat for a second. My law clerk told me you had an issue.

JUROR NO. 6: Yes.

THE COURT: With timing. What's that?

JUROR NO. 6: My son just informed me through letter that he will be graduating from boot camp on February 4, it is a Friday. That's the only issue I've got.

THE COURT: Where is that?

JUROR NO. 6: Great Lakes, Illinois.

THE COURT: So, what is the day that you say is the -- day or days that you say would be the conflict?

JUROR NO. 6: February 4th. It would be one day. Like I would leave on the 3rd and go to the 4th. It is a Friday.

THE COURT: All right. If we either finish before that date or we're able to accommodate that day for you, could you serve?

JUROR NO. 6: Yes.

THE COURT: All right. Let me talk to the lawyers about it and I'll give you further instructions with regard to that later on. At least we have a little bit of time. I want to see what our schedule looks like and see whether or not it makes sense that if we proceed with you, and we don't sit that day. We're a team. We can't work unless everybody is here. I'd have to give everybody that day off and that would push us back until the next week. Let me talk to the lawyers and why don't you wait and I'll give you further instructions.

JUROR NO. 6: Yes, sir.

(Juror No. 6 not present)

THE COURT: What's your reaction at this point?

MR. ROOS: I guess the first question is, did we get 17 jurors?

THE COURT: We can't hold 17 jurors. We'll have to get rid of somebody. Our choice is either him, her or Alternate No. 5.

MR. ROOS: That's why I ask. If we have 17, we have to get rid of someone. If the Court is inclined to let the juror who has the work conflict go, we are okay picking that person as the person of the 17 to be excused. It sounds like for the second juror that was up here, that we could, if we're still even going at that point, we could just take that Friday off.

THE COURT: Mr. Gottlieb, what's your position?

MR. GOTTLIEB: Your Honor, thank you. My position is the same as I indicated before. In fact during the questioning of Juror No. 8, she clearly did not react vociferously that there was no way she could possibly miss this press conference. In fact, your Honor, if you listen to hear what she's talking about is this director apparently wants somebody to hold his hand. He is a little unsteady, he is a little unsure. They fired the publicist. She did not indicate that she could not serve. She was bringing something to the Court's attention. We don't believe -- we selected these jurors, we took our time, and they were then selected. To have her now be excused for the reason that she presented, there is simply no basis for it.

I would ask that she remain, Juror No. 8. The next juror, I'm sorry. Juror 6. Clearly that doesn't seem to be a problem. Because who knows where we're going to be. And if it is a real problem and we need to take a Friday off, I think we probably all would relish that thought during a lengthy trial.

So, I would ask that they both remain and that, as we had planned, the last juror be excused today, your Honor.

THE COURT: Okay. Well, I'm not inclined to excuse her, unless you both agree. And the simpler thing would be to keep the alternate that we know has no problem and doesn't give me an excuse or reason not to be here.

The things that I don't like in trials are unknown factors. I agree with you, Mr. Gottlieb, that I don't think

that that's a good excuse at this point. But she is an unknown factor, and I don't know, I would hope she can still be an attentive and appropriate juror. But, if you want to take the chance with her, when you know we have the alternate, I'll tell her, I'll take the weight and tell her she has to serve. But whatever, obviously, that would be at the defense request.

So, I'm giving you an option of taking somebody who you know who has no problem, as opposed to somebody who doesn't want to be here.

MR. GOTTLIEB: Your Honor, I appreciate you giving me that option. I would ask that both jurors continue to serve, be sworn and continue, your Honor.

THE COURT: All right. The government want to be heard any further?

MR. ROOS: I think your Honor has our position. One thing I am not sure we heard was whether this costs her money. But, she didn't say it, so it probably doesn't.

THE COURT: Okay. Well, then I'm prepared, I'm prepared to go ahead and excuse the fifth alternate that we had. And tell the jurors that they will all be serving. If it gets any more complicated than what we already have, or you reconsider that position, we could always excuse her, we would be down one alternate during the trial. But, she's talking about next Monday and Tuesday.

So, I'm going to bring them all in and tell them that

they will be serving. So, what I'm going to do is I don't want a reaction from that juror. I'm going to leave Alternate No. 5 in the jury room and bring up the other 16. Obviously, sooner or later it's going to dawn on everybody and particularly on her that we excused him and made her stay. But, for now, I'm not going to bring him up, I'll tell him to wait in the jury room. I'll bring up the other 16, we'll seat them in the appropriate seats, we'll swear them in, give preliminary instructions, and we'll start with the opening statement.

Who is going to make the opening statement on behalf of the government?

MR. BURNETT: I am, your Honor.

THE COURT: Did you want me to introduce you, Ms. Rothman, or do you want to do that yourselves?

MS. ROTHMAN: I'm sorry, your Honor?

THE COURT: Did you, you weren't here last week so I wanted to know whether you wanted me to introduce you or whether or not that's going to be handled in opening statement.

MS. ROTHMAN: Maybe your Honor could just reintroduce counsel to the jury.

THE COURT: I don't need to go through everybody.

MS. ROTHMAN: I think it's fine. Thank you for the offer.

THE COURT: If you need a short break, take it now. Otherwise I'll bring the jurors up.

MR. GOTTLIEB: Your Honor, just very quickly, Mr. Janey will be doing the opening. But I would like to point out before, if we are going to go into witnesses immediately, which I know we will, before cross-examination, as I understand it from my group here, the deputy in charge of the way the electronics works has said there is a problem with the cable here. So for cross-examination, we need a -- they're going to repair so we can use and cross-examine and display exhibits. So I wanted your Honor to know that until that is done, we wouldn't be able to begin cross.

THE COURT: I didn't know there was a problem.

MR. JANEY: If I could just add briefly, he didn't want to disturb the Court. So there are two gentlemen who are going to come up. We tested it, everything worked during testing, but the cable in the floor was changed and he has to fix it.

THE COURT: All right.

MR. ROOS: Apparently it's not working for the government either.

THE COURT: Do we need that for opening statements?

MR. BURNETT: No, your Honor.

MR. JANEY: Not for the defense, your Honor.

THE COURT: All right. Then let's get the jury.

MR. BURNETT: Your Honor, just a moment for the restroom.

THE COURT: Sure.

(Pause)

THE COURT: Are we ready to proceed?

MR. GOTTLIEB: We're ready.

THE COURT: Let's bring the jury in then.

(Jury present)

THE COURT: Swear in the jurors, please.

(A jury of 12 and four alternates sworn)

THE COURT: Ladies and gentlemen, members of the jury, at this point I'm required by law to instruct you generally concerning your basic functions, duties, and certain rules which apply to every jury so you'll be better able to assess and weigh the evidence as it's presented and reach a proper verdict.

Now the trial has commenced with the selection of the jury. At this point, you will be the jury that will be hearing this case. I cannot accommodate at this point any further personal or professional reasons not to continue on this trial, so I would ask that you give your full attention to this case, and, as best you can, adjust your own personal and professional lives in a manner consistent with what I've indicated to you this trial, the length of this trial and how we should proceed.

Again, I think the case will take about three weeks to try. I'm going to try to keep us moving along so we can speed up that time and not get behind schedule, but at this point,

this is going to be the priority and commitment for the next three weeks, at least that period of time.

Now, ladies and gentlemen, the trial has commenced with the selection of the jury as I indicated. So the next step in the trial will be an opening statement by the government to outline for you what the prosecution intends to prove by way of evidence in the case. After counsel for the government makes their opening statement, counsel for the defendant, if they desire, may also, but is not required to, make an opening statement.

What counsel for either side says in opening statement is not evidence. You may consider the opening statement as a preview of what each side intends to prove by way of evidence in the case.

Now, after the opening statement or statements, the assistant United States attorneys will present one or more witnesses who will be questioned by them. This is called direct examination. After the assistant United States attorney completes their questioning of the witness, defense counsel will be given an opportunity to question that witness. This is called cross-examination. And after the government has concluded the calling of its witnesses and the introduction of any exhibits which are admissible into evidence, the defendant may, but is not required to, offer evidence in his own defense. After both sides rest, the government's attorney may make a

closing argument followed by the closing argument of the defendant's attorney, then the government may have a brief rebuttal in response, and then I will instruct you on the law and you will retire to deliberate for the purpose of reaching a verdict. This is a general outline of the trial procedure.

I ask you to listen carefully to the testimony. You don't need to take any notes. You'll have the court reporter read back any testimony and give you any exhibits during your deliberation that you may want to see. But, it's up to you whether you want to take any notes, but it's not necessary.

The evidence in this case consists of testimony of the witnesses under oath, and exhibits which are admitted into evidence, plus any stipulations agreed upon by the attorneys.

Questions in and of themselves are not evidence. Therefore, you cannot infer any fact from the mere asking of a question. It is the answer coupled with the question that constitutes evidence. For example, if a witness was asked a question "Don't you own an automobile," and the witness answers "No," you may not infer from the mere asking of the question that the witness does own an automobile.

During the course of the trial, the assistant United States attorney or defense counsel may object to a question or answer on the ground that somehow it is improper or inadmissible. If I sustain the objection, this means I believe the question or the answer was in some way improper. If an

answer has already been given, I'll instruct you to disregard it and therefore the answer is no longer evidence in the case. If I overrule the objection, then it means that the question is proper and I'll permit it to be answered. Or, if already answered, I will permit the answer to remain as evidence in the case.

Please do not resent the fact that an attorney makes an objection. This is their duty, and do not hold it against them if I rule against either side.

As I will explain to you in detail in my instructions at the end of the case, as jurors in this case, you are the sole judges of the facts, and I am the sole judge of the law. And you must accept the law as I give it to you, without hesitation or reservation, even if you privately disagree with me.

You must keep an open mind. Throughout the trial you must not converse among yourselves or with anyone else upon any subject connected with the trial. You must neither offer or express an opinion about the guilt or innocence of the defendant or reach any conclusion about what the verdict should be until I finally give the case to you. You must not read or listen to any accounts or discussions of the case in the event that it's reported by newspapers or other news media. You must not visit or view any promises or place where the offense charged was allegedly committed or any other place or premises

involved in the case. You must not do any research or investigation on your own about the case. You must decide this case solely on the evidence presented at this trial. And you must speak to no one about the case until the trial is completely ended, and you must promptly report to the Court any incident within your knowledge involving an attempt by any person to speak with any members of the jury about the case.

During the trial, you should not speak with any of the parties in this case, nor any individuals associated with them. They are instructed not to speak with you. So don't consider it rude if they see you outside of this courtroom and don't acknowledge your presence. Obviously, if someone were to see you speaking to one of the parties involved in the case, they might draw an improper inference, even though it might be a perfectly innocent conversation unrelated to the case.

Now, at this point, I want to keep us on schedule. We'll now proceed with the next step in the trial, which will be the opening statement by the government.

MR. BURNETT: Thank you, your Honor.

For years, bad pharmacies flooded communities across the northeast and right here in New York City with dangerous drugs. Powerful opioids like OxyContin and fentanyl. Those bad pharmacies sold drugs illegally fueling addiction, ruining lives.

That man, Laurence Doud, the defendant, supplied

opioids to many of those pharmacies. He and the people who worked for him shipped the opioids, knowing that some of those pharmacies were selling them illegally, and turning a blind eye to clear signs that others were breaking the law. Then he had his employees lie to the government about what they were doing.

The defendant was the CEO of Rochester Drug Cooperative, or RDC. The defendant's company shipped prescription drugs to pharmacies, including tens of millions of opioids.

The defendant knew that his company had a responsibility when it sold those drugs. A duty to make sure they didn't go to pharmacies that were breaking the law. But the defendant, he didn't care about the responsibilities that came along with shipping dangerous drugs. He didn't care about taking the steps to make sure pharmacies weren't breaking the law, like investigating pharmacies, cutting them off when there were signs they were acting illegally, and reporting them to law enforcement. That was bad for his business.

So the defendant put sales over safety. He directed his employees to keep shipping drugs to pharmacies they knew were selling those drugs illegally, and to pharmacies where there were clear signs of law breaking. And then he had his employees cover it up.

The defendant made clear that his employees should not report bad pharmacies to the Drug Enforcement Administration --

the DEA -- even though they were required to. And at the defendant's direction, his company lied to the DEA. He had his employees tell the DEA that things were above board, that his company followed a written policy and investigated pharmacies before selling them opioids, that his company would stop selling dangerous drugs to bad pharmacies. Those were lies.

That's what the defendant did. He worked with others to illegally sell dangerous drugs, and had his employees lie to the DEA to cover it up.

This morning I'm going to talk for a few minutes about what we expect you'll see in this trial. First, I'll tell you in more detail about what we expect the evidence will show, and then I'll tell you about how we plan to prove it to you.

(Continued on next page)

MR. BURNETT: First, so what will the evidence show you'll start by learning a bit about how the pharmaceutical industry works, the company that makes the drug. The manufacturers usually don't sell those drugs right to pharmacies. Instead, they sell them to a company called a distributor.

That distributor buys drugs from the manufacturers, then resells them to the pharmacies. The defendant was the head of one of those drug distributors, a company called Rochester Drug Co-Operative or RDC. You'll hear that RDC was a small company, only about 50 people in its main office, and the defendant kept a close watch over what went on there.

Now, even though RDC was a small company, it still sold lots of drugs, billions of dollars worth. Some of those drugs were harmless, like allergy medications or Tylenol, but RDC also sold hundreds of millions of dollars worth of opioids. Those powerful addictive pain medications I mentioned earlier. You probably heard of them, drugs like oxycodone, fentanyl or percocet.

The defendant didn't have to get into the business of making money by selling opioids, he chose to. And because he chose to sell those drugs, he took on responsibilities. Because opioids are so dangerous, you'll learn that they're called controlled substances under the law. That means there are rules, strict rules about how they can be sold, and those

rules apply to every one who sells opioids, including the defendant and his company.

You see, opioids can be abused. There are bad doctors and pharmacies out there who prescribe and sell opioids to people without any real medical need for them, to drug dealers or to people suffering from addictions. Selling opioids like that is illegal. It's called diversion, and diversion is against the law.

The rules against diversion, against selling opioids illegally also apply to distributors like the defendant's company. You'll hear that the drug distributors play an important role. Remember, they're the ones who sell to the pharmacies. So under the law, the defendants's company had to maintain effective control against diversion.

And what does that mean? Well, you'll hear it just means, the defendant's company needed to make sure it was shipping drugs to pharmacies that were selling them legally. They couldn't just ship drugs to bad pharmacies, to pharmacies that were breaking the law and wash their heads of responsibility. It didn't work that way.

Instead, the rules required the defendant's company to investigate their pharmacy customers, to make sure those customers weren't acting illegally and to have a system in place to detect something called suspicious orders, orders where there was a red flag assigned that the pharmacy might be

breaking the law.

If the defendant's company found a red flag, it was supposed to investigate. And if the order was suspicious, report it to the DEA and not ship the drugs. You'll learn that the defendant understood his responsibilities. He knew the rules. He also knew the dangers that came along with selling opioids, that there were bad doctors and pharmacies out there. People would do anything to make a buck, even if it meant selling those drugs to drug dealers or people suffering from addiction.

He knew that people across the country were dieing from opioids, but the defendant, he broke the rules. Why? Greed. You see, the defendant had a deal with his company, and under that deal the more money his company made, the more money he made. You'll learn that investigating a pharmacy's customers' opioid purchases or holding up an order, that was bad for his bottom line.

His company would lose those opioid sales, or even worse, lose all of that pharmacies business. So what did he do? You'll learn the defendant corrupted his company. He made sure that the rules wouldn't get in the way of his sales. The defendant started by undermining RDC's compliance department. That's the department that was supposed to make sure RDC followed the law.

He put a person in charge of compliance who had no

experience, not a clue what he was doing. Then the defendant made sure the head of compliance knew that the defendant called the shots. The compliance should not stop pharmacies from getting opioids unless the defendant said it was okay. Then at the defendant's direction, his company ignored its written policies about preventing diversion. Policies that it had given to the DEA.

You'll learn that RDC had some policies that gave the impression it was careful about selling opioids. They even had lawyers come in and help write one of those policies. Said all the right things, said that RDC would look out for red flags of diversion; that when it saw a red flag, it would stop to investigate; that it would stop selling to suspicious pharmacies and report those pharmacies to the DEA.

Those policies, they weren't worth the paper they were printed on. You'll hear the defendant gave different marching orders to his employees in the compliance department. He told them, compliance was a waste of time and money, that his company shouldn't risk losing business by investigating opioid orders, no pharmacy could get cut off from opioids without the defendant's approval, and RDC should not report pharmacies to the DEA.

The employees in compliance, they did what the defendant wanted. He was the boss and his demands were clear. His company should keep opioids going out the door, even if it

meant they were going to pharmacies that were selling those drugs illegally or showed serious red flags of diversion. So the defendant's employees kept the drugs flowing.

Take just a few examples. RDC's policies said that if a pharmacy ordered over a certain amount of opioids, RDC would stop selling to investigate. Hitting that limit was a sign the pharmacy might be misusing the drugs. Again and again, the defendant's employees saw pharmacies go over those limits but kept selling. No investigation.

RDC's policies said another red flag was if a pharmacy sold to suspicious doctors. Those are bad doctors, doctors who had no business prescribing opioids or who seem to give opioids to every patient who walked in the door. The defendant's employees knew certain pharmacies were magnets for those bad doctors, but they kept selling at his direction. The defendant supervised all of this. The red flags were obvious.

The defendant's own son who worked at the company even told the defendant that RDC had some very suspicious customers, but the defendant directed compliance to keep shipping opioids. And you'll hear that at the same time he pushed for even more dangerous practices. The defendant had RDC start selling opioids to pharmacies that other distributors had cut off from those drugs.

He told his employees that when RDC got a new customer, they should start selling opioids to that pharmacy

right away without doing any research on whether that pharmacy was illegally diverting drugs. The defendant's scheme, it worked. His company's opioid sales skyrocketed. Revenues from opioids grew over six times. And because pharmacies don't just buy opioids, lots of other sales came along with it. The defendant, he pocketed millions of dollars, money from bonuses tied to RDC's sales.

Now, the defendant knew that he had to be careful. The DEA was on the look out for distributors who were selling to bad pharmacies. That's why he had a compliance department and a written policy. You'll even hear that every once in a while, RDC actually stopped selling opioids to a pharmacy, usually when it was so obviously breaking the law that the defendant and his employees worried that pharmacy would get caught by the DEA.

But make no mistake, that's not a meaningful compliance process. You'll hear that the rules didn't allow the defendant to pick and choose when he wanted to stop diversion. He didn't get to decide when he wanted to follow the law. He had to do it all the time with every pharmacy that his company sold opioids to. But instead, his company shipped out thousands of dangerous opioid orders, ignoring red flags that they were going to pharmacies where diversion was happening.

Now, remember what I mentioned earlier, selling

opioids to bad pharmacies, that was only one part of the scheme. The other part was lying, lying to the DEA, and the two parts of that scheme went together hand and hand. Keep in mind, the DEA was out looking for distributors who were breaking the law. You'll learn that the DEA asked the defendant's company about how it made sure it was taking steps to prevent diversion. That's where those policies I mentioned earlier, the one that the defendant's company didn't follow, that's where it came in handy.

The defendant's employees gave that policy to the DEA and said they followed it. That was a lie. They routinely ignored that policy at the defendant's direction. The defendant also had his employees hide critical information from the DEA. Distributors like RDC are supposed to report suspicious opioid orders from pharmacies. Those reports are an important tool that the DEA uses to stop pharmacies from selling drugs illegally.

But the defendant, he didn't want his customers getting reported to the DEA, so his employees didn't do it. In the years when RDC's opioid sales were skyrocketing, when the defendant's company was selling to bad pharmacies across the northeast, the company filed just a handful of those suspicious order reports. That's what the evidence will show, that the defendant with the help of others sold opioids to pharmacies knowing that some of those pharmacies were selling the drugs

illegally and turning a blind eye to red flags of diversion at others. Then, they lied to the DEA to protect themselves and their pharmacy customers.

For those acts, the defendant is charged in two counts. First, for conspiracy or agreeing with others to illegally distribute controlled substances; and second, for agreeing with others to defraud or lie to the DEA.

So how are we going to prove it to you? Over the course of this trial, you'll hear from a number of witnesses. You'll hear from a former supervisor in the DEA. She'll tell you about the rules that distributors have to follow when they sell opioids and how the DEA told distributors about those rules. You'll hear from an employee in the compliance department. She'll tell you all the ways the defendant's company broke those rules, how his company shipped opioids to pharmacies knowing that those pharmacies had the telltale sign of diversion.

She'll tell you about times when the defendant came into her office and had her ship controlled substance orders even though she didn't want to, didn't want to because she knew it was against RDC's written policies, and because those pharmacies showed clear signs of diversion.

You'll hear from the man the defendant made head of compliance. He'll tell you that the direction to sell to bad pharmacies came from the top, from the defendant, that the

defendant told him how to run the compliance department, that the defendant made it clear, the compliance employees should ship opioids to pharmacies, even when there were red flags that those pharmacies were selling the drugs illegally.

He'll also tell you that at the defendant's direction, he and others lied to the DEA. They lied about the way RDC investigated suspicious pharmacies and they hid information from the DEA about those pharmacies. Now both of those compliance employees I mentioned, they committed crimes at RDC. They went along with the defendant's schemes to keep their jobs.

The head of compliance, for instance, will tell you that he's pled guilty to illegally selling opioids and lying to the DEA and he's cooperating with the government in the hopes of receiving a lighter sentence. You should pay careful attention to what these witnesses say, just like with any other witness at trial. See if their testimony lines up with the other evidence.

What is that other evidence? Well, you'll hear from an expert, an economist who analyzed data about RDC's opioids sales. He'll tell you that RDC's opioid sales increased dramatically while the defendant was in charge and that the company shipped out thousands of opioid orders that had been flagged for investigation. He'll also show you information about some of the pharmacies that RDC sold to, how those

pharmacies had many of the problems that RDC's own policy said were red flags for diversion. You'll hear some examples, examples of what's behind those red flags that RDC was selling drugs to, bad pharmacies that were diverting them. They were hurting people. You'll hear from a pharmacy owner who bought opioids from RDC and sold those pills illegally.

He'll tell you that he sold pills to drug dealers straight out of his pharmacy, and he'll tell you that when the defendant was in charge of RDC, the pharmacy owner got his pills from the defendant's company, no questions asked. You'll hear from a victim of opioid addiction. Someone who became addicted to oxycodone and got those pills without any real medical need for them.

You'll hear that she got her pills at another pharmacy that RDC supplied. You'll see RDC's documents and reports, the due diligence policies that RDC did not follow, reports listing thousands of opioid orders that RDC flagged for investigation but then shipped without pausing to investigate. The defendant's employment contracts which paid him more money as his company sold more drugs, hard evidence of his motives to commit these crimes.

You'll see the defendant's own words in black and white in emails he sent while he was at RDC. You'll see that he described compliance as a waste of time and money, that he got angry if employees tried to follow RDC's written compliance

policies, that he supervised RDC's sales closely as the company shipped more and more opioids to pharmacies that showed clear signs of selling those drugs illegally.

You'll hear that when he found out the DEA might be paying less attention to distributors like his company, that he directed his compliance employees to start shipping opioids to new pharmacy customers without any due diligence, even though RDC's policies, the written policies, said the exact opposite.

Finally, you'll see emails between employees in the compliance department where they discussed problems at the pharmacies where the defendant's company was selling opioids.

This made employees sick to ship opioids to some of those pharmacies, but you'll see that they kept sending the drugs, that they knew the defendant wanted opioid orders sent even if it meant selling them to pharmacies they knew were selling the drugs illegally or that showed red flags of diversion, so they did what he wanted.

Now, the evidence that I've outlined, it won't come in like a movie in chronological order. It's going to come in piece by piece, and different witnesses will tell you different parts of what happened. At the end of this trial, you'll have an opportunity to put those pieces together. Between now and then, I'd like to ask you to do three things.

First, pay close attention to the evidence.

Second, follow Judge Daniel's instructions on the law.

And third, use your common sense, the same common sense and good judgment you use everyday in your own lives.

If you do those three things, you'll reach the only verdict consistent with the evidence and the law, that the defendant is guilty.

THE COURT: Mr. Janey, would you like to make an opening statement.

MR. JANEY: Yes, your Honor. Thank you.

May it please the Court, the Honorable Judge Daniels, counsel, ladies and gentlemen.

Well, I too listened to what the government claims this case is about and what the government claims the evidence will show. By the time this trial is over, this is what you will conclude, the defendant, Laurence Doud, Larry Doud, is falsely accused of the charged crimes in this case. Based on the evidence, the government's own witnesses, the cross-examination of those witnesses, the direct examination of defendant witnesses, testimony from experts, the documents admitted in evidence in this case, you'll hear, you'll read, you will learn and come to know that the accusation that Larry Doud is a drug dealer is absurd.

You, the jury, not the prosecutors, you will decide what really happened based on the evidence, not based on argument, but on actual proveable facts. At the end of this trial, the evidence will have established that the government,

that the government failed to show beyond a reasonable doubt that Larry Doud knowingly and intentionally agreed and joined with others at RDC to illegally distribute oxycodone and fentanyl or to defraud the United States government.

The defendant Larry Doud was the chief executive officer of RDC, the most senior manager. You will learn that when Larry Doud retired as CEO after 30 years of experience and service starting as a sales manager, a graduate of Keystone Junior College in Scranton, Pennsylvania, that the company employed a 140 people, 140 jobs, and generated more than $2 billion in sales. It had become one of the largest distributors to pharmacies in the country.

You will learn that among the hundreds of products sold by RDC, some of the products were Oxycodone, the 30 milligram pack, and fentanyl, the spray placed commonly under the tongue. Oxycodone and fentanyl are pain medications as you'll hear. And as a distributor, as the evidence will show, RDC played an important role in helping people get their pain medication.

As a distributor, RDC bought the oxycodone and fentanyl from the companies that make the drug, the manufacturers. RDC in turn sold and distributed the drugs to pharmacies. Now, you'll hear discussion about large quantities of drugs in this case, and that might seem in and of itself unusual; however, you will learn that RDC had a license from

the Drug Enforcement Administration, the DEA, to be in possession of and distribute these drugs to others that had a similar license.

You will learn, ladies and gentlemen, that Larry Doud respected that license, contrary to the government's narrative. You will hear from witnesses and learn from documents that RDC had a compliance program to oversee distribution of these drugs to pharmacies under its license. It wasn't a perfect program, but you will learn that any idea that the compliance program was a sham or a front for peddling drugs illegally is false.

Ladies and gentlemen, that's important because we're in criminal court. You'll learn why it doesn't matter whether the compliance program was perfect. Here in this case, it is important because the government alleges that Larry Doud knowingly and intentionally joined a conspiracy to send oxycodone and fentanyl to the pharmacy customers of RDC, even though he knew -- that Larry Doud knew that those prescriptions were not for a medically justified purpose, that the drugs were being abused, that he entered into an agreement with his employees to send those drugs to pharmacies even though he knew they were being abused.

However, by the end of this trial, the evidence will show that Larry Doud never knowingly and intentionally participated in an illegal scheme to distribute oxycodone or fentanyl. That is what this case is about, whether Larry Doud,

this man, knowingly and intentionally joined a conspiracy to distribute narcotics illegally and to defraud the government of the United States.

Ladies and gentlemen, my name is Derrelle Janey. I along with my colleagues Robert Gottlieb and Paul Townsend seated here at the defense table, we represent Larry Doud. In this trial, we will ask you to ask lots of critical questions, critical questions about the evidence put before you by the government, both the documents they show you and the witnesses the government puts in the witness box.

Critical questions about what the government presents are important for several reasons. First, the evidence will show that employees at RDC sometimes pointed out to Larry Doud that certain customers were buying large amounts of oxycodone and fentanyl. Sometimes employees at RDC pointed out to Larry Doud that certain RDC pharmacy customers were permitting patients to pay only in cash for their prescription. Sometimes they pointed out to Larry Doud that sometimes patients frequented out of state pharmacies, and those pharmacies fulfilled those out of state prescriptions. These are the so-called red flags.

You will learn that none of this means that Larry Doud was an illegal narcotics dealer. You will learn and the evidence will show what Larry Doud actually did when presented with red flag information, and that what he did was consistent

with the law. You will learn how Larry Doud's employed consultants to visit pharmacies to ensure they were following the law.

You will learn that consultant recommendations were imposed on pharmacies after those inspections. You will learn that countless, countless, pharmacies were shut down under Larry Doud's watch as CEO, and you will conclude that Larry Doud, the person here in this case charged with illegally distributing narcotics is falsely accused by the government of the United States.

There will be lots of names of pharmacies described and referred to in this case. In any of those instances, please ask yourself, what is being said about what Larry Doud, what Larry Doud did in connection with that pharmacy.

Plainfield pharmacy, for example, ask yourself, the evidence will show that when presented with information that Plainfield showed the risk that it was selling oxycodone for a non-medical purpose, Larry Doud agreed with other RDC employees to shut down distribution to that pharmacy.

Vogel pharmacy, when RDC's consultants themselves, former DEA agents, recommended further audits of Vogel, Larry Doud was all over it. You will find that the emails show it. Not just my attorney argument, you will hear. You'll hear Larry Doud say, keep me posted, be sure to update me on the audits. The evidence will show that when, for example,

presented with information about Browns Drug, a potential new customer wanting to acquire oxycodone. Larry Doud expressed to his employees that he wanted to try to do business with Browns, but did not want to take any risk from the DEA in doing so.

So, again, ladies and gentlemen, we ask that you ask critical questions, critical questions about the documents put before you by the prosecutors in this case, about the witness testimony and the motivations. And the evidence will show with respect to a group of pharmacies called Linden Care, Larry Doud time and time again agreed and pushed for close monitoring of the Linden Care demand for oxycodone.

You'll hear that sometimes Larry Doud could be a demanding CEO, demanding more information from his compliance department before pharmacy customer might be cut off for oxycodone, pushing his team to think about the sales relationship. But you will conclude that none of that meant based on the evidence that Larry Doud knowingly and intentionally joined a conspiracy to illegally distribute oxycodone or fentanyl or to defraud the government of the United States.

The evidence will clearly show that not only did Larry Doud ask lots of questions to his employees, that not only did he caution employees to follow the law, the evidence will also show that Larry Doud caused consultants, former agents of the DEA, to go out to different parts of the country to visit RDC's

pharmacy customers to ensure that they were dispensing oxycodone and fentanyl to patients who needed help managing their pain, severe enough pain requiring daily around the clock treatment, chronic pain, lower back pain, cancer related pain, arthritis related pain, breakthrough pain.

You will see with your own eyes that the former DEA agent hired by RDC audited Linden Care, RDC's largest purchaser of oxycodone and fentanyl four times. And dates, ladies and gentlemen, are important in this case. They are important because the chronology is important to understand what Larry Doud did and when Larry Doud did it.

So you will hear the dates of the Linden Care audits by the RDC consultant. You will hear that those dates occurred during the timeframe in which Larry Doud was supposedly involved in a conspiracy that resulted in Linden Care diverting drugs; July 2013, March 2014, May 2014, September 2014, each time the former DEA agent turn consultant met with the Linden Care chief operating officer, the chief compliance officer, the supervising pharmacist and their DEA regulatory compliance director, all the head honchos.

You'll learn the consultants' recommendation to RDC. With regards to required DEA records, Linden Care has met all the required regulations imposed by federal laws and regulations pertaining to records required by DEA of a pharmacy each and every time the former DEA agent consultant visited

Linden Care. You will learn that he never reported Linden Care was or likely was selling oxycodone or fentanyl for non-medical purposes none of the four times.

And importantly, ladies and gentlemen, the evidence will show and you will hear that the DEA itself, the actual government agency never told Larry Doud, be careful, caution, Linden Care is selling oxycodone or fentanyl for non-medical purposes.

In fact, you will learn and I will read and you will hear that none of the DEA investigations of Linden Care during the timeframe in this indictment in this case ever found Linden Care was diverting oxycodone.

Not in 2013 when you will learn that the DEA concluded the investigation, found no evidence of a pattern of disregard for the regulations of the Controlled Substances Act; not in 2014 when it concluded no finding of a problem with diversion of oxycodone after review of two months worth of records and a review of thousands of oxycodone prescriptions.

This is important because one of the key pharmacy examples you will hear about in this case is Linden Care and the diversion of oxycodone at Linden Care supposedly with oxycodone linden Care obtained from RDC. This is important because this case is about whether Larry Doud acted criminally, criminally, knowingly and intentionally joined with others at RDC to help Linden Care, for example, the company's largest

customer, sell oxycodone for none-medical purposes illegally, illegally.

As you critically listen to the government's witnesses and as you examine the evidence, please listen for why these criminal charges were brought against Larry Doud, were they brought because he knowingly and intentionally joined with others to sell oxycodone and fentanyl illegitimately and for person financial gain; or as the government described in its narrative this morning, for greed; or are there other reasons that work.

And as for Larry Doud's personal financial gain or his greed, you will hear about Larry Doud's compensation at RDC that he had a long-term employment contract negotiated with and approved by the board of directors at RDC.

Yes, you will hear that during the timeframe of the indictment Larry Doud made more money than he had made at the beginning of the indictment period. Yes, in years when oxycodone and fentanyl shipments to pharmacy customers increased, Larry Doud's yearend bonus also increased.

However, importantly, you will learn incredibly that Larry Doud's bonus compensation had practically nothing to do with increased sales or oxycodone or fentanyl contrary to the government's entire narrative in this case.

Instead, his bonus compensation was driven by none-controlled drugs, drugs that have nothing to do with the

allegations in this case. That is what you will hear from the experts. That is what you will learn from the evidence that drugs like lipitor, a cholesterol lowering drug; drugs like albuterol, a drug that provides relief from asthma attack. Those are the drugs you will learn that drove Larry Doud's bonus compensation.

This is important because you will hear that the government's theory of this case is that Larry Doud was motivated to distribute illicit drugs out of greed. You will hear -- and ladies and gentlemen, the evidence will certainly show, that such a narrative is absolutely false. You will learn that the actual analysis shows that narrative to be totally wrong.

Finally, ladies and gentlemen, at the close of this trial, taking into account all that the evidence will show, the witness testimony, the documents, the questions, the cross-examinations, the evidence will show that this man, Laurence Doud, III, Larry Doud is falsely accused by the government of the United States.

You will hear and you will learn from the evidence that Laurence Doud, III, did not knowingly and intentionally join with others at RDC to illegally distribute oxycodone or fentanyl, and he certainly did not intentionally defraud our government.

Ladies and gentlemen, your role as juror is actually

even bigger than your role as a mere citizen. As a juror, Judge Daniels will give you instructions and further explain your duty as a juror. That is part of his role as the presiding judge in this case. However, there is no question that you will be deciding the guilt or innocence of this man in criminal court on criminal charges. That is an incredible responsibility.

I only request that you take it seriously. Larry Doud requests that you take it seriously because his life is at stake. Your Honor, thank you.

THE COURT: All right. Ladies and gentlemen, we'll take a 10 minute break before we hear the first witness. Don't discuss the case. Keep an open mind. They'll take you to the jury room and we'll bring you back out in 10 minutes.

(Jury not present)

MS. ROTHMAN: Your Honor, I didn't want to object during Mr. Janey's opening, but I do think that his statement about the motives for the government's prosecutor here was entirely inappropriate.

THE COURT: You'll have to quote me that language that you're referring to.

MS. ROTHMAN: Yes, your Honor. What I recall Mr. Janey saying is he being charged because he committed a crime -- and I'm paraphrasing -- or is there something else, another reason, something else going on here.

I think the implication here is that the motives by the government are improper. And as the Court knows, it is entirely inappropriate for the defense to put the government on trial or impeach the motive of the government here. So I would hope we're not going to see more of that type of argument during cross examination or during direct examination or closing arguments from defense counsel.

THE COURT: Did you want to respond, Mr. Janey?

MR. JANEY: Very simply, your Honor. I disagree that there was any type of improper motive assigned to the government. I think the record will reflect that there was a comment in the government's opening that the motivation on the part of the defendant was greed, and I addressed that, and that's a part of the evidence that we have long presumed that they would present.

THE COURT: All right.

MS. ROTHMAN: I'm not sure that's actually responsive. The defendant's motive are important here and relevant. He is on trial. The government is not on trial. I believe the Court will instruct the jury of that before they begin their deliberations. Any suggestion that the government's prosecution here is improper is inappropriate.

THE COURT: Well, are we getting daily copy?

MS. ROTHMAN: Yes, your Honor.

THE COURT: Why don't you, when we get the daily copy,

just point to me what pages that you're referring to so we're all clear about what the issue is, and I think everyone here knows what their responsibilities are and stay within those boundaries.

MR. GOTTLIEB: Your Honor, before we break.

THE COURT: Yes.

MR. GOTTLIEB: In regard to the witnesses, I would like to put on the record, while we have agreed to a number of stipulations, there's also an agreement that the government is not going to reference or elicit any testimony with regard to a civil matter, a civil fine that was paid by RDC prior to the indictment. I just wanted to make sure that that information will not be elicited in the government's case in chief.

MR. ROOS: I think we may have to go back and have further discussions with counsel. Our agreement was that we're not going to try to introduce the document of any of the corporate resolutions.

MR. GOTTLIEB: Your Honor, we have an agreement that the government in its case in chief was not going to elicit testimony with regard to a unrelated -- that have to deal with administrative, an RDC fine.

If there's any question about that, I would ask that we take a break and we'll pull out the emails.

THE COURT: If you have such an agreement in writing, you should talk to each other first. And then before we

continue with the jury, I'll get to this issue and we'll address it.

MR. ROOS: Two things, your Honor. We did exchange emails. If my recollection of what the email say is wrong, then shame on me. We should certainly consult what the government wrote previously.

And second, I think it's okay because I don't think the first three witnesses are going to go to this at all. To the extent the government did not agree to that and defense wants to make a motion, there certainly is time for that. It's not going to --

THE COURT: Why don't you agree to what you agreed to or agree to disagree and then you can show me the emails that you said this is what was done in writing, or you can tell me what the nature of the discussion was before I have to resolve the motion to include or exclude this testimony.

MR. GOTTLIEB: I'm happy to do that as long as nothing is going to be raised this afternoon. We don't have to rush now to gather the --

MR. ROOS: The first three witnesses are Carter, Masseth, Castro, and it's not going to come up during any of them.

THE COURT: Let's resolve it as early as possible.

All right.

(Recess)

(In open court; jury not present)

THE COURT: Is there anything we need to address now that the jurors are on their way?

MS. ROTHMAN: Not from the government, your Honor.

MR. GOTTLIEB: No, your Honor.

THE COURT: Did you get the room, the jury room?

MR. GOTTLIEB: Yes, thank you.

MR. ROOS: Just for our planning purposes, what time do you typically take lunch and how late do you plan to go?

THE COURT: I take lunch between 12:30 and 1 o'clock. We've ordered lunch from 12:30, so somewhere between 12:30 and 12:45 we hope the lunch will be here. Maybe an hour five, an hour and 10 minutes for lunch.

Jury entering.

(Jury present)

THE COURT: Would you call the government's first witness.

MS. ROTHMAN: Yes, your Honor. The government calls Ruth Carter.

THE COURT: Step up into the box. You can remove your mask while you are in the box.

(Witness sworn)

THE COURT: You can be seated. Would you state and spell your name for the court reporter.

THE WITNESS: It's Ruth Carter. And that's R-U-T-H

C-A-R-T-E-R.

THE COURT: You can inquire.

MS. ROTHMAN: Thank you, your Honor.

RUTH CARTER,

called as a witness by the Government,

having been duly sworn, testified as follows:

DIRECT EXAMINATION

BY MS. ROTHMAN:

Q. Good afternoon, Ms. Carter?

A. Good afternoon.

Q. Where do you live?

A. I live in northern Virginia.

Q. What do you do for work?

A. I am a consultant, a pharmaceutical consultant.

Q. Where did you work before becoming a consultant?

A. I worked for the Drug Enforcement Administration for 31, almost 31 years.

Q. What is the Drug Enforcement Administration?

A. The Drug Enforcement Administration is the federal agency responsible for enforcing the drug laws, the federal drug laws.

Q. Did your work in the DEA focus in a particular area?

A. Yes. I worked in the diversion control division, which is the division of the DEA that enforces the regulations and the law regarding pharmaceutical controlled substances.

Q. I want to start with some of the different roles that you

held at the DEA, Ms. Carter.

In what year did you join the DEA?

A. 1988.

Q. What was your first role?

A. I was a diversion investigator in the Oklahoma City office.

Q. What did you do as a diversion investigator?

A. We conducted administrative, civil, and criminal investigations against DEA registrants who were violating the Controlled Substances Act.

Q. In sort of layman's terms, what types of cases did you investigate?

A. So the cases could involve doctors that were writing bad prescriptions or it could involve a pharmacist that was knowingly filling bad prescriptions or the pharmacist could be selling drugs out the back door. Those types of investigations.

Q. After your time in Oklahoma City, where did you go?

A. I was then, I was transferred to the Riverside, California, office, and I worked there as a diversion investigator as well.

Q. After that, what was your next role at the DEA?

A. I was transferred to the Las Vegas office, and I became the group supervisor for the diversion group in the Las Vegas office.

Q. What did you do as the group supervisor there?

A. So the group supervisor just coordinates the group. So

they manage, ensure that the investigations are being conducted in the appropriate manner, and that investigations are actually being conducted when they need to be conducted.

Q. For how long were you in that role?

A. I was in the Las Vegas office for -- two years I believe. No, four years. I'm sorry, four years.

Q. What did you do after that?

A. After that, I was transferred to DEA headquarters where I worked in our domestic chemical division.

Q. After your time at headquarters, where did you go?

A. I then went back to the field and worked in the Seattle field division, where I was the group supervisor for the diversion group in Seattle as well.

Q. After your time in Seattle, where did you go?

A. After Seattle I went back to DEA headquarters, and I ultimately became a section chief in the diversion control division at our DEA headquarters.

Q. What types of things did you do at headquarters in that second stint there?

A. I was as a section chief. I was in the regulatory drafting section initially. And in that section, I oversaw the rescheduling of hydrocodone from Schedule II to Schedule III, and I oversaw the scheduling of tramadol. And then, after that I was put in the liaison and policy section, and in that section I dealt with the registrants in the field. The liaison

unit, pretty much it is the -- liaises with the field, basically. And that was what I, that was my role.

Q. What types of things did you do in the liaison policy section of the DEA?

A. So, I attended a lot of national conferences, well over 100 national conferences during my time while I was the section chief of that section. I gave a lot of presentations to DEA registrants regarding the requirements of the regulations. And a lot of the conferences, they were either DEA sponsored or industry sponsored. I went to universities and taught students that were going to be graduating from either dental school or medical school.

Q. Were the obligations placed on distributors one of the topics discussed in those presentations you gave?

A. Yes, absolutely. So, if -- the topics depend upon the audience. So, if the audience was distributors, then our primary topic was the distributors' role in the supply chain and what their responsibilities were in order to keep their DEA registration.

Q. We'll talk about those responsibilities a bit later in your testimony.

Was that your last role at the DEA?

A. No. After that, I was transferred to be the diversion program manager in the Washington field division, which is located in Washington, D.C.

Q. What do you did in that role?
A. That role, I reported directly to our special agent in charge, and I handled and coordinated all matters relating to pharmaceutical controlled substances, and I oversaw all of our investigations for the entire division, which did include Maryland, Virginia, and the District of Columbia.
Q. When did you leave the DEA?
A. I left June 8 of 2019.
Q. Ms. Carter, during your time at the DEA, did you have any involvement in the investigation of Laurence Doud or Rochester Drug Co-Operative for diversion?
A. No.
Q. So, Ms. Carter, I want to start with some basics. Are you familiar with the Controlled Substances Act?
A. Yes.
Q. What is that act?
A. It's the federal law that regulates the controlled substances.
Q. How does the Controlled Substances Act, or the CSA, regulate controlled substances in this country?
A. So, the Controlled Substances Act classifies drugs, the controlled substances, into schedules. It also requires entities and individuals who want to handle controlled substances legally, they are required by the Controlled Substances Act to be registered with the DEA.

Q. So let's talk about the schedules first. How many schedules are there under the CSA?

A. There are five schedules under the CSA, and the Schedule I controlled substances are illegal, so they cannot be legally used or distributed or possessed in the United States. And then the Sections II through V are the pharmaceutical controlled substances that you have to have a DEA registration in order to handle.

Q. Focusing just for a moment on Schedule I. What's an example of a drug that would fall within Schedule I?

A. Heroin.

Q. So now let's focus on Schedule II. What types of drugs go into Schedule II?

A. So the Schedule II drugs are the most highly abused and the most -- they have the most potential for abuse and the most potential for addiction. So the Schedule II controlled substances have narcotics and non-narcotics. The narcotics do contain -- some of the narcotics are opioids. And these are the drugs that are the most abused drugs in the United States, the Schedule II drugs.

Q. Can an individual legally possess a Schedule II controlled substance?

A. The only way an individual can legally possess a Schedule II controlled substance is to pursuant to a prescription that was issued by a DEA -- a DEA registered practitioner.

Q. What are some common Schedule II prescription drugs?
A. Oxycodone, hydrocodone, fentanyl, Dilaudid.
Q. What is the medical purpose of those prescription drugs?
A. The medical purpose for those drugs is pain.
Q. Are they dangerous?
A. They are very dangerous. That's why they're controlled substances. So, in order to -- any of the drugs that are scheduled in Schedules II through V are dangerous controlled substances.

MS. ROTHMAN: Ms. Drescher, can you please pull up for the witness what's been marked as Government Exhibit 624, 634, 631, and then 635.

Q. And Ms. Carter, if you'll take a moment and look at your screen at those four image as Ms. Drescher cycles through them and I'll ask you a few questions. Let's start with Government Exhibit 634, if we can Ms. Drescher.

Let's do 631. That's okay.

A. Okay.
Q. Do you recognize this image?
A. Yes, this is -- I do recognize this.
Q. What is it an image of?
A. This is an image of Subsys. The packaging of Subsys and the actual Subsys.
Q. Is that a fair and accurate depiction of Subsys?
A. Yes.

MS. ROTHMAN: The government offers Government Exhibit 631 into evidence.

THE COURT: Any objection?

MR. GOTTLIEB: No objection.

THE COURT: It's admitted in evidence.

(Government's Exhibit 631 received in evidence)

MS. ROTHMAN: May we publish to the jury?

THE COURT: Yes.

MS. ROTHMAN: Thank you, your Honor.

Q. I think it's now on everyone's screen.

Now that the jury can see, can you remind us what we are looking at here, Ms. Carter?

A. This is a picture of Subsys.

Q. What is the medical purpose of Subsys?

A. Subsys is used for breakthrough cancer pain.

Q. What is the controlled substance found within Subsys?

A. It's fentanyl.

Q. Is it dangerous?

A. Yes, it's very dangerous.

Q. Is it addictive?

A. Very addictive.

Q. We can take that down and pull up what's been marked for identification as Government Exhibit 635, please.

Let's do 624. That's okay.

Q. Do you recognize this image, Ms. Carter?

A. Yes.
Q. What is it an image of?
A. This is an image of a bottle of OxyContin 30 milligram and it's got two tablets on the side.
Q. Is it a fair and accurate depiction of OxyContin?
A. Yes.
MS. ROTHMAN: The government offers 624 into evidence.
THE COURT: Any objection?
MR. GOTTLIEB: No.
THE COURT: It will be admitted in evidence.
(Government's Exhibit 624 received in evidence)
MS. ROTHMAN: May we publish to the jury?
THE COURT: Yes.
MS. ROTHMAN: Thank you, your Honor.
Q. Now that we all can see, Ms. Carter, what are we looking at?
A. This is a picture of a bottle of OxyContin, 30 milligram, 100 tablets, and to the right are two actual tablets of OxyContin.
Q. What is OxyContin?
A. OxyContin is a Schedule II opioid. It contain oxycodone.
Q. What is the relationship between OxyContin that we are seeing here and oxycodone?
A. Well, this is -- OxyContin is an extended release form of oxycodone.

Q. Is it a branded name of oxycodone?
A. It is also a branded name. It is the same active ingredient, that being oxycodone.
Q. What is the medical purpose of this drug?
A. This is used for pain as well.
Q. Is it dangerous?
A. Very dangerous.
Q. Is it addictive?
A. Very addictive.
Q. Looking at the photograph, there is a kind of a C with the number II inside. What does that refer to?
A. Any time you have a controlled substance, on the bottle they're required to label -- on the label it's required to have the schedule listed, so that this is a C with II, Roman numeral II, which mean it is a Schedule II controlled substance.
Q. Ms. Carter, we'll leave that on the screen, but I am going to ask you to look at your binder which is at the front. There are two photographs that are marked for identification as Government Exhibit 634 and 635. Do you see those?
A. Yes.
Q. What are they?
A. So, the 634 is a picture of a bottle of oxycodone 30 milligram. And 635 is a picture of a bottle of oxycodone 20 milligram and oxycodone 40 milligram.
Q. Is that a fair and accurate depictions of those oxycodone

products?

A. Yes.

MS. ROTHMAN: At this time the government offers into evidence Government Exhibits 634 and 635.

THE COURT: Any objection?

MR. GOTTLIEB: Your Honor, I believe I have an objection but it wasn't on the screen so let me just check.

THE COURT: Sure.

MR. GOTTLIEB: No objection, your Honor.

THE COURT: It will be admitted into evidence.

(Government's Exhibit 634, 635 received in evidence)

MS. ROTHMAN: May I publish to the jury?

THE COURT: Yes.

Q. Ms. Carter, what are we looking at in Government Exhibit 634?

A. It is a bottle of oxycodone, 30 milligrams.

Q. Again, how does oxycodone compare to the OxyContin that we just saw?

A. Well, it's the same active ingredient, which is oxycodone. And I believe the other one was 30 milligrams as well, so it is the same milligrams. Just that the OxyContin was an extended release and it was a branded product by a certain company. And this is a generic form of oxycodone.

Q. And the 30 milligram, what does that refer to, Ms. Carter?

A. The 30 milligram is the amount of oxycodone that's

contained in that tablet.

Q. How do drugs like oxycodone or Subsys compare to over-the-counter drugs like Tylenol?

A. Well, there is really no comparison. So, the oxycodone and Subsys and OxyContin are controlled substances, and they're dangerous controlled substances. They're highly addictive, they are highly abused. And they have been Schedule II controlled substances, which means they're regulated by the DEA. And the DEA only regulates the drugs that are dangerous. So all of the drugs are dangerous. But these particular drugs are in Schedule II, which is the most stringent schedule and these are the most -- the most highly addictive drugs that the DEA regulates.

Q. How do they compare to an illicit drug like heroin?

A. Well, these drugs are similar -- similar to heroin. In fact, the heroin is a semisynthetic opioid that's made from the poppy plant, and so is oxycodone. Oxycodone is a semisynthetic opioid. They both come from the poppy plant. So they're very similar.

Q. What does the DEA regulate?

A. Well, the purpose of the regulation is to ensure that the drugs aren't diverted from legal channels into illicit channels, so they're not abused any more than they can potentially be abused when they are used legally.

Q. In your time at the DEA, did you notice any trends with

respect to the frequency that prescription pain medication like oxycodone was being prescribed?

A. Yes. So, when I first started at the DEA, there really wasn't, people didn't even know what these drugs were. The average person didn't even know it. But everyone knows what these drugs are today, because we've been in the middle of an opioid epidemic and a public health crisis for years now.

And what happened is, doctors started writing more prescriptions for these drugs, and then they started being dispensed more by the pharmacies, and a lot of time -- when I say writing more prescriptions, they were writing them illegally. So they started writing them illegally, and people started getting addicted to them, and then the pharmacies started filling the prescriptions, and then the distributors started selling the prescriptions to the pharmacies.

So, it just became a cycle that ended up being -- that culminated into the opioid epidemic.

Q. Can you give the jury a sense of how big of a problem this was.

A. Well, it is a huge problem, because just since, between 2000 and 2019, according to the CDC, I mean, almost 850,000 people have died of a drug overdose. And out of those, if you look at just prescription opioids, and that's the drugs like these, it's almost 250,000 people that they can attribute to having died from these drugs. And when I say they can

attribute it, that means they listed the cause of death as being a prescription opioid. That's not going to cover it all. There are a lot more people that likely died from the opioids, but the coroner maybe didn't catch it or didn't list it as the cause of death.

Q. What, if any, relationship is there between these prescription pain medications and illicit drugs like heroin, for example?

A. Can you repeat that?

Q. So does somebody who gets addicted to these types of pain medications only use prescription pain medications?

A. No. Unfortunately, what happens when they get addicted to these, these opioids like the oxycodone, the fentanyl, the Dilaudids, when they get addicted to those, they become -- there is many reasons that they end up switching to illicit drugs like heroin and fentanyl. But, one of the primary reasons is because they, their habits, as they continue to take the drug, they develop a tolerance and then they need more and more of the drug. As they need more and more of the drugs, the drugs become too expensive for them to be able to afford to pay for the pills, because pills cost more. It is a lot cheaper to get the heroin off the street and to get the fentanyl off street.

So that's what we've seen. If you look at what's happened, the prescription opioids have decreased and declined,

but the heroin and fentanyl has risen dramatically.

Q. Thank you, Ms. Carter. So we spoke about the scheduling of controlled substances. You also mentioned that the CSA places restrictions on who can sell and distribute controlled substances. So I want to talk about that now.

Are you familiar with the term DEA registrant?

A. Yes.

Q. What does that term refer to?

A. A DEA registrant is any entity or individual who is registered by the DEA to handle controlled substances.

Q. If you're not a DEA registrant, are you allowed to distribute or sell controlled substances?

A. No.

Q. If you lose your DEA registration, are you allowed to distribute or sell controlled substances?

A. No.

Q. We'll come back to this later. But, does the fact that a company has a DEA registration mean that they're complying with their obligations under the law?

A. No.

Q. I'm going to pull up for the witness what's been marked for identification as Government Exhibit 901.

Do you see that on your screen?

A. I do.

Q. Do you recognize this?

A. Yes.
Q. What is it?
A. This is a depiction of the supply chain, that's the supply chain that pretty much from the manufacturer down to the patient as far as the -- how the controlled substances get from the manufacturer all the way to the patient.
Q. Is it a fair and accurate depiction of that supply chain?
A. Yes.
MS. ROTHMAN: The government offers Government Exhibit 901 into evidence.
THE COURT: Any objection?
MR. GOTTLIEB: No, your Honor.
THE COURT: It will be admitted into evidence.
(Government's Exhibit 901 received in evidence)
MS. ROTHMAN: May we publish to the jury?
THE COURT: Yes.
MS. ROTHMAN: Thank you.
Q. Now that we all can see Government Exhibit 901. What are we looking at, Ms. Carter?
A. So, again, this is a depiction of the supply chain, and it shows you how the drug gets from the manufacturer, and they are the ones that take the raw material and create the substances. And in this instance, we are talking about opioids, so creates the controlled substances.
So the manufacturer creates the controlled substances,

they then sell them typically to wholesale distributors and also other types of distributors. They sell them to the distributors, and then the distributors take those and they distribute those to retail pharmacies, hospitals, and all of the entities that ultimately will dispense those to the ultimate user, which is the patient.

Q. There is one other entity on this chart, the medical provider. What's their role in the supply chain of getting controlled substances from manufacturer to patient?

A. Well, the medical provider has to write the prescription or the order, if they are in the hospital. But they have to write the prescription for the controlled substance to the patient.

Q. Who on this chain is required to register with the DEA in connection with controlled substances?

A. So everyone on this chain has to be registered with the DEA, except the patient.

Q. Are there certain requirements that come with being authorized to distribute controlled substances as a registrant?

A. Yes. Each registrant in the supply chain has specific responsibilities and requirements, based upon their position within the supply chain.

Q. We are going to talk about those requirements in a moment, but before we do, I want to focus on the wholesale distributor for a moment.

Are the wholesale distributors required to sell

controlled substances?

A. No. They're not required. It is a voluntary decision to sell controlled substances in the United States.

Q. Do some distributors not sell controlled substances?

A. Yes. There are multiples and hundreds and hundreds of distributors out there that do not sell controlled substances at all.

Q. I want to talk about some requirements placed on DEA registrants. Have you heard of something called ARCOS data?

A. Yes.

Q. What is ARCOS data?

A. ARCOS data is data -- is data that the distributors and manufacturers transmit to the DEA. It is transactions by those entities that they transmit to the DEA. And the transactions they transmit are all Schedule II transactions, and then all Schedule III narcotic transactions. All of those are transmitted to the DEA.

Q. Who is required to report ARCOS data?

A. The manufacturers and the distributors.

Q. Why does the DEA require manufacturers and distributors to report ARCOS data?

A. Well, the data is required to be reported because it gives the -- first of all, it provides the information to the DEA, the DEA can then use that information to look at trends across the country, look at if there are pockets of areas in the

country where there are issues. This data can help provide the DEA that picture.

But one thing I would note, it is not realtime data. It does get transmitted after the fact.

Q. Are registrants like wholesalers also subject to inspection by the DEA?

A. Yes.

Q. How often dos that happen?

A. So the DEA conducts what they call scheduled investigations, and those are -- during my time at the DEA those were conducted between every three to five years, so just depended on what the policy was at that time. But when I left the DEA, it was every three years.

Q. Can you give us a sense of what happens during those inspections?

A. So those inspections are, they conduct -- they conduct a review of the physical security at the facility, as far as it relates to the controlled substances. They conduct an accountability audit, and the audit is conducted eight to 10 drugs. Eight to 10 controlled substances. And then they also review the recordkeeping that is done by the registrant.

Q. In your experience, are those scheduled investigations a comprehensive assessment of whether or not a particular distributor is following the law?

A. No. I mean, in -- you will -- in those inspections you

could see that certain laws aren't being followed, such as some of the recordkeeping requirements aren't being followed. But it's not going to give you an over-comprehensive view of whether or not the registrant, particularly when it relates to distributors, whether or not they're maintaining effective controls against diversion. The scheduled investigation typically won't give you that comprehensive review.

Q. Why not?

A. Because the scheduled investigation is an investigation that it is almost like a picture in time. And so, you're looking at that point of time that you're looking at, is that point of time, obviously. But you also, when the DEA comes in, they're reliant upon what the registrant gives them. So they ask the registrant for the data and the information. And then the registrant provides that information to the DEA. So the DEA won't know if information is not provided, and they only know what information is provided.

The only other way that they would know would be to get a search warrant, and they wouldn't be able to do that unless they were conducting a criminal investigation.

Q. I now want to talk about diversion, Ms. Carter. Is there a particular division -- withdrawn.

What is diversion?

A. Well, diversion is any time the controlled substances, and in this case the opioids, are removed from this legitimate

supply chain that we just went over. Any time they were removed from the supply chain and go into the illicit market, that's called diversion.

Q. Is there a particular division of the DEA that focuses on diversion?

A. Yes. It is called the diversion control division.

Q. Is that where you spent all of your time at the DEA?

A. Yes, all in my entire career.

Q. What is the mission of the diversion control division of the DEA?

A. So the mission is to prevent, investigate and prevent the diversion of controlled substances from this legitimate supply chain into the legitimate market. While at the same time ensuring that there is an adequate amount of controlled substances available for legitimate medical, educational, and industrial purposes, scientific purposes.

Q. Do registrants such as wholesale distributors have any responsibilities to prevent diversion?

A. Yes. Each registrant in the supply chain that's depicted, they each have their own set of responsibilities.

Q. So, let's talk about those responsibilities. Why don't we start with the medical provider on the right side of the chart. What is his or her responsibility to prevent diversion?

A. The medical provider's responsibility is to only write prescriptions for controlled substances if there is a

legitimate medical need or purpose for that controlled substance. So if there's not a legitimate medical need for the controlled substance, they shouldn't write a prescription for that controlled substance.

Q. Let's talk about the pharmacy. What is a pharmacy's responsibility to prevent diversion?

A. So the pharmacy's responsibility is what's called a corresponding responsibility. And that responsibility is they are to review the prescriptions that are presented by patients to the pharmacy from the medical providers, and they are to review the facts and circumstances surrounding the prescriptions, and then they have a corresponding responsibility to use their professional judgment and determine whether or not they believe that prescription is actually in fact legitimate. And if they don't feel that prescription is legitimate, they should not fill that prescription.

Q. Thank you. Let me ask you about the wholesale distributor. What is the wholesale distributor's responsibility with respect to diversion?

A. So the wholesale distributor has a responsibility to maintain effective controls against diversion. And that involves, part of maintaining effective controls against diversion is to have a system, they are required to design a system that identifies to them suspicious orders, and they are to report those suspicious orders to the DEA upon discovery.

And when part -- the system doesn't consist of just identifying orders. The orders -- when they look, they have to look at the orders, they have to investigate the orders to determine if the orders that they flag are indeed suspicious. If they cannot dispel the suspicion, that then they should not ship those orders and those orders should be reported to the DEA as suspicious.

The other thing part of their system should include the proper resources for their compliance department. They should provide proper training to their employees. And they should have all of the tools they need to conduct onsite investigations. I mean, so it's not just identifying the order. The system involves the review of the order, and making sure that that order is actually suspicious or is it not.

Q. I want to unpack some of what you said, Ms. Carter. What is a suspicious order?

A. A suspicious order is an order that is of unusual size, frequency or pattern.

Q. When you say an order of an unusual size, what do you mean by that?

A. Well, of an unusual quantity. "Quantity" is probably a word that's more easily understood. But the volume of the prescriptions. So is the prescription -- is the distribution to the pharmacy. So, is this volume higher than it should be. Is it -- is it excessive. Is it excessive for that area, that

demographic area. So is the population, are they ordering above average of what a normal pharmacy orders for that demographic population.

Q. You also mentioned pattern. What does a pattern mean with respect to a suspicious order?

A. A pattern is they should compare -- one example of a pattern would be if they're ordering above the average of other pharmacies that are of the same size, and again, way above the average or above the average. If it is even above the average, that's a red flag and is something they should look at. That's an example of a pattern.

Q. What about frequency, what does that mean?

A. Frequency just refers to the number of times they order. So, it's how many times they've ordered, is it changing.

Q. What is a distributor required to do under the law with respect to suspicious orders?

A. Well, the requirements are that they are to review the order, investigate it, and determine if it's suspicious. And if it is suspicious, if they can't dispel the suspicion that originally caused it to be flagged by their system, then they should not ship that order. And they shouldn't ship any subsequent orders until and unless they can dispel that suspicion. So if they never dispel the suspicion, they shouldn't ship the orders to that customer.

Q. Is the distributor required to report that order to anyone?

A. Yes. They are required to report that order to the DEA upon discovery.

Q. Why does the DEA require that suspicious orders be reported?

A. Well, the DEA requires the orders be reported because the federal regulations require that -- the federal law requires they be reported.

Q. I guess more broadly, what is the purpose of the reporting requirement? Thank you, Ms. Carter.

A. Yes. So the purpose of the reporting would be to alert the DEA that this particular pharmacy or customer is placing suspicious orders, and it would alert the DEA so the DEA could conduct investigations.

Q. Does the DEA inform distributors that they are required to have a system in place to disclose suspicious orders?

A. Yes.

Q. Does the DEA inform distributors that they are required to report suspicious orders to the DEA?

A. Yes.

Q. How does the DEA inform wholesale distributors of these obligations?

A. The DEA informs their registrants of their obligations from the time they're registered. So when they first are registered, the DEA actually sends investigators out and they meet with the company at the facility. They go to their

facility. They meet with them, they look at their facility. They then go over what the requirements are at that time. But then after that, the DEA has sent guidance letters, the DEA holds DEA-sponsored conferences, the DEA also sends out representatives to attend national conferences.

Q. Does the DEA tell distributors what their suspicious order monitoring program needs to look like?

A. No. The DEA, the DEA -- because the regulation requires that the registrant design the system, and it does say "the registrant shall design," the DEA does not tell the registrant how to design its suspicious order monitoring system. And this is because the -- every registrant's business is different. And the DEA relies upon the registrant to know its own business, to know its own customers, and to also know what the customer has purchased in the past. So, the DEA doesn't have all that information. So the DEA wouldn't be able to design each registrant's system. Every system could be different. No registrant system has to be the same.

Q. Does a distributor having a system that monitors order size alone mean that that distributor is maintaining effective controls against diversion?

A. No.

Q. Why not?

A. Because just having the system doesn't mean that the registrant is maintaining effective controls against diversion.

Because you can have a system in place, but if you are not following the system, if you're not actually carrying through with your requirements and identifying the suspicious orders, investigating the suspicious orders, and then if you can't dispel the suspicions then report those suspicious orders to the DEA, then your system is not effective. Therefore, it's not maintaining effective controls against diversion.

Q. If a distributor allows a little bit of diversion to occur, is that maintaining effective controls against diversion?

A. No. A little -- a distributor shouldn't allow any diversion to occur. So if a distributor sees diversion, they should immediately cease all sales to that registrant. If it is diversion that they see, and it is a result of orders that have been sent to that registrant over a period of time, then they probably need to take a strong look at their system, because their system obviously has issues.

MS. ROTHMAN: Your Honor, I'm about to move into a topic about red flags of diversion. Would you like me to keep going or should I stop for lunch?

THE COURT: Go another five, 10 minutes. I think the lunches should be here soon.

MS. ROTHMAN: Thank you, your Honor.

Q. Are you familiar with the phrase red flags of diversion?

A. Yes.

Q. What does that mean?

A. Red flags are just, they're warning signs. So signals, this is something you need to stop and take a look at.

Q. I am going to ask you about some red flags of diversion. But before I do, how is a distributor able to see these red flags of diversion?

A. Well, the distributor can see the red flags by looking at their own sales information, which is their own -- the information of the sales that they're making to their customers. They can see a lot of red flags by just reviewing their sales information and looking at it closely and comparing it to the customer and the information that they should have gathered about that customer before they even brought the customer on board as a customer. The other way, I mean, in what they can't see from their sales information, they can see from dispensing information that they can get from their customer. Should get from their customer.

Q. What is dispensing data or information?

A. Dispensing data is data that shows what's been dispensed by a pharmacy. So, the distributor can ask for that data, for lack of a better way to get it. But the data, it will show what was dispensed, on what date, what the drugs were. They should be obtaining dispensing data that shows the prescriber name. The only thing they should leave off of this dispensing information is the patient name, because that's protected by HIPAA and they should not get that information from the

pharmacy. But they should definitely get the prescriber information.

Q. So now I want to ask you about some red flags of diversion. What are some red flags of diversion that a distributor can see?

A. Well, some red flags that a distributor can see by just looking at its own data. One of them is to compare the amount of controlled substances that they are dispensing to a customer, compare that as compared to the non-controlled substances. So what is the percentage that they're selling of controlled substances to that customer.

So there's certain percentages, if it's going above 20 percent, then that's, they should be taking a very strong look at that, because that's a significant red flag. And actually, I mean, I would say 15 percent is when the red flags begin.

Q. Why is a high percentage of controlled substance sales a red flag of diversion?

A. Because a normal retail pharmacy has, they sell all substances, anything that can be prescribed, you know, they like to have -- the most prescribed items they are going to keep in stock. They are going to keep a little bit in stock. And a normal pharmacy has a wide variety of substances. And the percentages of controlled substances is significantly lower than the percentages of non-controlled substances that are

dispensed.

Q. What's the problem with a pharmacy primarily or significantly dispensing controlled substances and not non-controlled substances?

A. If they're dispensing high percentages of controlled substances, it is highly likely that the prescriptions that they're receiving, that they're dispensing are coming from pill mills. And if that's the case, they shouldn't be dispensing those prescriptions.

Q. Ms. Carter, what is a pill mill?

A. A pill mill is a doctor, it could be one doctor, it could be multiple doctors, but doctors that are basically writing bad prescriptions.

Q. So what are some other red flags of diversion, separate and apart from the percentage of controlled substances being dispensed at a pharmacy?

A. Another red flag is the high percentage of cash payments for controlled substances.

Q. Why is that a red flag of diversion?

A. Because typically, the normal customer has some form of assistance with their payment, whether it be insurance, Medicare, Medicaid, payment vouchers, or, you know, credit vouchers. Whatever, there is usually some type of assistance. It is not that common to use cash to pay for prescriptions. And a lot of times drug seekers will use cash because either,

number one, they can no longer use their insurance because they -- the insurance only lets you purchase a 30-day supply for a 30-day period. Or, they don't want to alert their insurance company that they're actually obtaining these controlled substances.

Q. What percentage of cash should be a red flag for a distributor?

A. I mean, any time they start getting into 8 to 10 percent of cash, then that should start being a red flag for cash purchasers of controlled substances.

Q. Other than a high percentage of controlled substances, and cash, what are some other red flags of diversion?

A. Some other red flags would be the -- the dosage, the high dosages versus low dosages. What that means is if a pharmacy is buying more oxycodone 30 milligrams than they're buying oxycodone 5 milligram, that's a significant red flag because most pharmacies, the average pharmacy is going to dispense more of the lower dose oxycodone than they will dispense oxycodone 30 milligram.

Q. Why is that a red flag of diversion?

A. That's a red flag because that would be abnormal, and that wouldn't be normal behavior of a retail pharmacy. And the oxycodone 30 milligram is a highly abused controlled substance and it's highly sought after by drug abusers. So when they're seeing more of those prescriptions than they are of 5

milligram, that's a significant red flag.

Q. Is there anything about pill count or the amount of pills in a prescription that could be seen as a red flag of diversion?

A. Yes. So high pill counts, I mean, depending on if the doctor's writing a prescription for a 90-day supply or a 30-day supply. The amounts should match what they're legally or what the standard medical practice is for that state. So, it should not -- the amount they prescribe should not exceed that.

Also, it should also not exceed the medical condition. So if it is a medical condition that's an acute condition and it's not going to last forever, then there is no reason they are getting a 90-day supply of that drug.

So the quantity is something that could be a very significant red flag.

Q. Could a 30-day supply of 180 pills of oxycodone 30, would that it be a red flag of diversion?

A. Yes.

Q. Why is that?

A. Because, that's, that's, that would be prescribing more than four tablets a day oxycodone 30 milligram, and that is a high, that would be a high dosage amount to prescribe.

Q. What about the location of the patients who are filling prescriptions as compared to the pharmacy or the medical provider?

A. The location of the pharmacy and the medical provider could be another red flag. So if the patients are traveling long distances from their residences, and it's not some type of oncology or some type of orthopedic specialist or some reason like that, then there is no reason, really, that a patient would travel long distances, unless typically it's to obtain the pills that they want to obtain, basically.

Q. Is there a certain percentage of out-of-state patients that would be a red flag of diversion for distributors?

A. Yes. So unless, unless it is a border state and they're literally right on the border, any out-of-state prescription at a pharmacy is going to be questioned by the pharmacy.

Q. Then, finally, what, if anything, about the doctors who are writing these prescriptions that could be a red flag of diversion?

A. Well, the doctors, if the doctors have been disciplined by the boards in the state, or they are, you know, arrested or convicted by a law enforcement entity, then that's obviously something that needs to be looked at immediately.

But even if a doctor is one of the doctors that -- so say they look at the dispensing records and they notice that one or two or even three or four of the practitioners are writing most of the oxycodone prescriptions, I am just using that as an example. If you see one or two doctors and they're writing the majority of those prescriptions, that's a

significant red flag, because you should see an average, like a normal amount that's disbursed by all the doctors. You shouldn't see it all, you know, relegated down to one or two doctors or a few doctors. That's a significant red flag and that should be investigated.

Q. Does a pharmacy need to have all of these red flags of diversion to be a concern for distributors?

A. No. Just one red flag should be a concern.

Q. What is a distributor supposed to do when they see red flags of diversion?

A. When they see the red flags, they should dispel that red flag. And if they can't dispel the suspicion surrounding that red flag, then they shouldn't ship the order.

Q. Is a distributor required to send controlled substances to their pharmacy customers?

A. No.

Q. Is a distributer allowed to rely upon the fact that a pharmacy has a DEA registration to sell controlled substances to that pharmacy?

A. No. Just having the DEA registration doesn't fulfill their requirement to maintain effective controls against diversion. They do have to maintain effective controls against diversion.

Q. Ms. Carter, is a distributor allowed to turn a blind eye to red flags of diversion?

A. No. Absolutely not.

Q. Why not?

A. Because they do -- the distributors in order -- their registration's predicated upon the fact they do have to maintain effective controls against diversion. And all of that involves the system that we've been talking about. They have to look at each order, if the order is suspicious, they have to dispel that suspicion or they should not ship that order.

MS. ROTHMAN: Now might be a good time to break for lunch.

THE COURT: We are going to take a lunch break at this time. Your lunch is running a little late. It should be here in the next five, 10 minutes.

Don't discuss the case. Keep an open mind. We'll continue at 2:10.

(Jury excused)

THE COURT: We'll continue at 2:10.

MS. ROTHMAN: May the witness step down?

THE COURT: Yes. Thank you.

(Luncheon recess)

(Continued on next page)

THE COURT: You can continue, Ms. Rothman.

MS. ROTHMAN: Thank you, your Honor.

BY MS. ROTHMAN:

Q. Welcome back, Ms. Carter.

A. Thank you.

Q. Before we broke for lunch, I asked you some questions about red flags of diversion. I now want to talk about some communications from the DEA that was sent to wholesale distributors.

Ms. Drescher, can you please pull up for the witness Government Exhibit 272 and then 273.

Q. Ms. Carter, do you recognize those documents?

A. Yes.

Q. What are they?

A. These are letters that were sent from the DEA to all DEA registered distributors and manufacturers in the United States.

Q. Are they fair and accurate copies of those letters?

A. Yes.

MS. ROTHMAN: Your Honor, the government offers Government 272 and 273 into evidence.

THE COURT: Any objection?

MR. GOTTLIEB: No objection, your Honor.

THE COURT: They will be entered into evidence.

(Government's Exhibits 272 and 273 received in evidence)

MS. ROTHMAN: Can you please pull for everyone Government 272 to start. Once it loads, I'll ask you to zoom in on the top third of the letter.

Thank you.

Q. All right. Ms. Carter, now that we all can see, let's go through this letter step by step. What's the date of the letter?

A. September 27, 2006.

Q. Who's the letter from?

A. The Drug Enforcement Administration.

Q. Who is this letter sent to?

A. Rochester Drug Co-Operative, Inc.

Q. Ms. Carter, can you please read the first paragraph of the letter beginning with this letter?

A. This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Administration to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.

Q. Thank you.

If we can zoom out and then zoom in on the second section. Thank you, Ms. Drescher.

I'm going to ask you to read the second paragraph in the background section.

A. The CSA was designed by Congress to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration, and as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion.

Distributors are, of course, one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general well fair of the American people.

Q. What does the closed system of drug distribution refer to in this paragraph?

A. The closed system of distribution is the -- it's the supply chain, if you will. The supply chain that we looked at earlier today, if you take all of those DEA registrants that's are within that supply chain, that's what called the closed system of distribution. There are certain requirements that are part of that closed system of distribution, such as the ARCOS and the recordkeeping that we talked about.

But in order for the drugs -- the goal is to ensure

that the drugs are not diverted outside of that closed system of distribution.

MS. ROTHMAN: Thank you. Ms. Drescher, if we go to the second page of this letter, and I'm going to ask you to zoom on the midportion of the letter with the paragraph that begins DEA regulation require.

Go down to one more paragraph. Thank you.

Q. Ms. Carter, I'm now going to ask you to read the portion of this letter that begins with, DEA regulations, and I'll ask you to read down to industrial channels?

A. The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically the regulations state in 21 C.F.R. 1301.74(b), the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances.

The registrant shall inform the field division of the administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of usual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

It bears emphasis that the foregoing reporting requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e), that a distributor maintain effective controls against diversion.

Thus, in addition to reporting all suspicious orders,

a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific and industrial channels.

Q. Just a few questions. In the first paragraph there's a citation to 21 C.F.R 1301.74(b), in general terms, what is that?

A. That's the federal regulations regarding the controlled substances regulations.

Q. And then in the third paragraph that begins, it bears emphasis that the foregoing reporting requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e), that a distributor maintain effective controls against diversion. What does that mean?

A. What this is saying is that, the distributors are required to have their suspicion order monitoring system, and they are required to identify and report suspicious orders. But this paragraph is pointing out that in addition to that, they are required to maintain effective controls against diversion. So just reporting is not the only thing that is required to be part of that system.

MS. ROTHMAN: If we can zoom out of this, Ms. Drescher, and zoom in on the paragraph that's second from the bottom. Thank you.

Q. I'm going to ask you to read this paragraph, Ms. Carter.

A. In a similar vein, given the requirement under Section 823 (e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a bind eye to the suspicious circumstances.

Again, to maintain effective controls against diversion, as Section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

MS. ROTHMAN: You can take that down and then turn to the third page of the letter. If we can highlight the title, circumstances that might be indicative of diversion.

Q. Before we talk about the content of this page, can you describe in broad strokes what is being discussed on this page of the letter?

A. Yes, these are circumstances that might be indicative. These are red flags.

Q. I'm going to focus on a few. I'm sorry, red flags of what?

A. Red flags that could indicate diversion.

Q. I'm going to focus on a few of them.

If we can zoom in on item number one in the first section.

Could I ask you to read this and explain what it's about, Ms. Carter?

A. Ordering excessive quantities of a limited variety of

controlled substances, e.g., ordering only phentermine, hydrocodone and alprazolam, while ordering few, if any, other drugs.

So this is referring to order patterns that I was referring to this morning. So if they're ordering certain controlled substances; say, for example, hydrocodone, oxycodone and alprazolam and they're ordering very little of other drugs, that's not a usual pattern for a pharmacy, that is a significant red flag.

Q. And if we can zoom out of that and zoom in on number four at the bottom of the first section.

Can you read this, Ms. Carter, and describe what's going on?

A. Ordering the same controlled substance from multiple distributors. When a pharmacy is ordering opioids for multiple distributors, they're typically doing that to try to avoid letting the distributor -- each of the distributors know how much they're really ordering, and that's why they would go to order for multiple. Because typically a retail pharmacy has one primary distributor, and then they usually have a secondary distributor that's available to them in the event their primary distributor can't supply them with the drugs that they need.

Q. If we can zoom in on the second section, the numbered bullets one to ten.

What does this section consist of, Ms. Carter?

A. This section is some suggested things that the distributor might ask the ordering pharmacy about an order.

Q. I'm going to ask you about number seven. Can you read that and explain what's going on there?

A. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy.

Q. What does that refer to?

A. That's referring to, when they're looking at the dispensing records of the pharmacy, are there one or more practitioners that are writing, just what it says, disproportionate shares. Are they writing the majority of the controlled substance prescription. Because if they are, again that's not normal and that's a significant red flag that needs to be looked at and inquired about.

Q. Let's highlight number one. If I can have you read that, Ms. Carter?

A. What percentage of the pharmacy's business does dispensing controlled substances constitute.

Q. What does that mean?

A. So again, that's referring to the percentage of the controlled substances as compared to the non-controlled substances. And I talked about that earlier today, but what percentage of -- this is saying, you need to inquire about this because if the percentage is high or above average, then that's

a red flag that needs to be explored.

MS. ROTHMAN: If we could zoom in on the final paragraph of this page.

Thank you, Ms. Drescher.

Q. If you could read that, Ms. Carter.

A. These questions are not all inclusive, nor will the answer to any of these questions necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).

Q. If we can take this down and please pull up what's in evidence as Government Exhibit 273. If we can zoom in on the top of the page again.

What are we looking at here, Ms. Carter?

A. This is another letter that was sent to all of the distributors and manufacturers in the United States by the DEA.

Q. What's the date of this letter?

A. December 27th of 2007.

Q. To whom was this letter sent?

A. This was sent to Rochester Drug Co-Operative, Inc.

Q. If I could ask you to read the first paragraph of the letter.

A. This letter is being sent to every entity in the United States registered with the Drug Enforcement Administration to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 C.F.R 1301.74(b).

MS. ROTHMAN: Zoom out and zoom in on the second paragraph.

Q. I ask you to read this paragraph up until the sentence that ends, suspicious orders.

A. In addition to, and not in lieu of, the general requirement under 21 U.S.C. 823, that manufacturers and distributors maintain effective controls against diversion. DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances.

Title 21 C.F.R 1301.74(b) specifically requires that a registrant design and operate a system to disclose to the registrant suspicious orders of controlled substances.

The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders.

MS. ROTHMAN: You can take that down. And if we can zoom in on the third paragraph.

Thank you, Ms. Drescher.

Q. I ask you to read that paragraph, please.

A. The regulation also requires that the registrant inform the local DEA division office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions, e.g., "excessive purchase report" or "high unit purchases," does not meet the regulatory requirement to report suspicious orders.

Registrants are reminded that their responsibility does not end merely with the filing of suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

Q. Ms. Carter, let me ask you, the reference in this paragraph to filing a monthly report of completed transactions, e.g., excessive purchase report or high unit purchases, what is that referring to?

A. Well, this is referring to -- during this time period, a lot of the distributors in the United States were sending monthly reports that they were -- some of them titled them excessive purchase reports, and they were sending these monthly

reports to the DEA after they had already shipped the controlled substances and there was no investigation being done. They were just sending the transactions. It was literally like hundreds of pages long of all the transactions that had hit a threshold for that month. And then, you know, they still shipped the order. They would just send in these transactions to the DEA.

Q. What's the problem with distributors doing that?

A. Well, because that's not reporting suspicious orders. That's just sending us, the DEA, a list of transactions. The suspicious orders, you know, before you determine it's suspicious, you need to look at it and determine that order is in fact suspicious. And then that order individually needs to be reported and it needs to be reported upon discovery and the order should not be shipped.

Q. Thank you.

MS. ROTHMAN: We can take that down and zoom in on the final paragraph.

Q. I'm going to ask you to read one sentence from this paragraph, the sentence the size of an order alone.

A. The size of an order alone, whether or not it is deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious.

Q. We can go to page two of the letter, and I'm going to ask you to read the top paragraph and then we are done with this

letter, Ms. Carter.

A. Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders; for example, a system that identifies orders as suspicious only if the total amount of controlled substances ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient.

This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of the relationship with the distributor.

Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially.

Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

Q. Can you just paraphrase what's going on in the first portion of this paragraph with respect to rigid formulas being insufficient?

A. Well, this is referring to, a lot of the distributors were using formulas that -- multipliers that were -- they would have an average and then they would have a multiplier. And then if the cumulative order for that month reached that quantity of pills, then they would call that order suspicious.

But the problem with that rigid formula is, it doesn't

identify orders of unusual pattern and orders of unusual frequency.

Q. Anything else insufficient with just having a formula and nothing else?

A. Could you repeat that.

Q. Anything else insufficient with just having a formula but nothing else as a wholesale distributor?

A. I'm having -- the very first part of the sentence.

Q. If a wholesale distributor only has a formula for monitoring suspicious orders, but no other due diligence in their compliance department, is that maintaining effective control against diversion?

MR. GOTTLIEB: Your Honor, objection.

THE COURT: No. She can answer that question.

A. That would not be sufficient.

MS. ROTHMAN: We can take that down, Ms. Drescher.

Q. Ms. Carter, I believe you testified that you were not involved in the investigation of Laurence Doud or Rochester Drug Cooperative, correct?

A. Correct.

Q. Have you been involved in other investigation of other wholesale distributors in your time at the DEA?

A. Yes.

Q. Did one of those investigation relate to Cardinal Health?

A. Yes.

Q. I want to ask about your involvement in that case. When did the --

MR. GOTTLIEB: Your Honor, objection. May we have a sidebar to explain.

THE COURT: Yes.

(At sidebar)

MR. GOTTLIEB: Your Honor, I object to the witness being asked about other investigations that she's had, asking her any details about those investigations. She, as I understood it, she is not being called as an expert witness for the purpose of giving an opinion. She was going to lay out, again my understanding was, what the law is, and what the requirements are, but what she has done and what her findings were in other cases involving other customers or distributors having nothing to do in connection with this case and should not be permitted.

THE COURT: Is this investigation at all related to RDC?

MS. ROTHMAN: Your Honor, I can explain, Government Exhibit 3 is an email that was forwarded to the defendant in relation to the Cardinal Health case, which Ms. Carter had direct involvement in. So Mr. Doud received an email in 2012 about the Cardinal Health case, about the DEA cracking down on wholesale distributors. That's going to come into evidence, goes to the defendant's knowledge of the responsibilities placed on wholesalers, the DEA's focus on those wholesalers. Ms. Carter was in Florida involved in that investigation. I'm going to ask her three questions.

THE COURT: What is she going to say?

MS. ROTHMAN: She's going to say she was involved in

Cardinal Health's investigation. It related to excessive oxycodone supplying to pharmacies in Florida, that Cardinal Health was failing to report suspicious orders, failing to comply with its obligation to maintain effective controls against diversion, and that's about it.

THE COURT: What is the connection to the defendant?

MS. ROTHMAN: What we're going to offer into evidence immediately after Ms. Carter is emails in which Mr. Doud receives information about Cardinal Health. She's providing some background.

THE COURT: She's not going to testify about the connection. What does the email say?

MS. ROTHMAN: Mr. Doud is forward an email in which -- we can pull it up -- in which the article is flagged that the DEA is looking into Cardinal Health. There's discussion about the obligations placed on wholesale distributors.

THE COURT: That's discussion between whom?

MS. ROTHMAN: The defendant and other employees of Rochester Drug Co-Operative who are alleged to be conspirators in the conspiracy. It goes directly to his knowledge of the obligation.

THE COURT: Who's going to testify to this?

MS. ROTHMAN: It's likely going to come in through a summary witness who is going to read some of those emails that Mr. Doud is copied on in which he receives these articles and

discussions. I believe that at least one of those emails, I believe Mr. Pietruszewski, who is another witness who will also talk about the increased crackdown on wholesale distributors that he and others at RDC have been informed of. It goes to the defendants obligation.

THE COURT: Can I see the email.

MS. ROTHMAN: Sure. Let me get it.

MR. GOTTLIEB: While they're getting it, can I make it very clear. I'm not objecting to an email that Mr. Doud maybe received, if you decide that that's relevant that he received it and if it meets the other evidentiary basis. What I'm objecting to is having a witness talk about her experience in another case where there was a finding as to give some credibility to a finding. It's an irrelevant issue.

I simply object to this witness testifying about another case. I'm not objecting to a subsequent email to Larry Doud which would go to his standing

MR. ROOS: Your Honor, one possibility could be the government can offer the emails now and then show them to the witness and say, can you explain what this Cardinal action was and could then provide the context. I think that's all Ms. Rothman is trying to get out.

MR. GOTTLIEB: What this witness's understanding, her background about something that was relaid to Larry Doud is irrelevant. That is not relevant, unless this witness spoke to

Larry Doud.

THE COURT: That I can't accept. The question is, who is in a position to explain what the Cardinal Health investigation was.

MS. ROTHMAN: That's Ms. Carter.

THE COURT: If they're going to, at some point, admit this document into evidence, which is an email about Cardinal Health.

MS. ROTHMAN: Ms. Carter is quoted in the article.

MR. GOTTLIEB: The email is the relevant piece of evidence. The email speaks for itself. What I mean by that if I can, if the email says Cardinal Health was indicted or was investigated because of whatever and that was relayed to Larry Doud, well that certainly can be considered relevant. But now to have the investigator talk about anything else about it goes beyond -- it does not impact what Larry Doud was told or knew. The email itself is relevant. I'm not objecting to the email.

But giving anything more than just reading the email because, that's what affected his state of mind.

THE COURT: I almost never accept the argument that the document speaks for itself. Document don't speak. People speak about documents and that's how you establish their relevance.

MR. GOTTLIEB: Your Honor knows exactly what I'm talking about. In this case, what's in the document is

relevant. This is sent to Larry Doud, and therefore, he read it. So whatever is in the document is what goes to his state of mind and would go to his knowledge. That's what I mean by that.

THE COURT: Well, if this is sent to him notifying him of an investigation that they were doing about Cardinal Health and it's otherwise going to come into evidence, the jury at least has the right to know what Cardinal Health's investigation was.

MR. GOTTLIEB: Respectfully, they are entitled to know what's in the email.

THE COURT: No. I have to stop you there. They're entitled to more than just what's on the piece of paper. They're entitled to relevant testimony about it and testimony that makes it clear, explains what this is about.

MR. GOTTLIEB: No. No. But if Mr. Doud wasn't given that information -- let's assume the only thing that Mr. Doud knows is what's is in the email. Somebody now telling the jury the blood and guts of the case like a homicide detective to talk about -- it would be like calling -- I'm not saying it's the same. It would be like calling a homicide detective to talk about, okay, the email was sent to this guy about a homicide, let me tell you about the homicide, blood and guts of the homicide. The facts are different, but that's about, judge, the state of mind based on the email.

THE COURT: I understand your argument, but what you just said is in the email. It says, this month the DEA accused Cardinal Health, a Fortune 500 company with $103 billion in revenue by endangering the public by selling excessive amounts of Oxycontin. Why is her statement that she investigated such a claim, why is that somehow inadmissible through her?

MR. GOTTLIEB: Your Honor, I did not object to the question, did you investigate. What I'm objecting is now if this email about Cardinal was given to Mr. Doud, so he's informed of that. It would be improper now for the investigator to go beyond this.

And quite frankly, to even testify about any of the facts because the relevant issue is that this document was given to Larry Doud.

THE COURT: I understand your argument in the abstract. I don't know specifically what information you're objecting to. What is it that you don't want her to say?

MR. GOTTLIEB: I don't want her to give any testimony --

THE COURT: Tell me what you don't want her to say.

MR. GOTTLIEB: Any of the underlying facts of the Cardinal investigation.

THE COURT: What don't you want her to say?

MR. GOTTLIEB: I don't know what she's going to say, your Honor.

THE COURT: I assume she's going to say what's in the letter. I'm trying to find out what information that comes out of this witness that you think is going to be somehow inadmissible or prejudicial given the fact that that's exactly what it says in this email that Mr. Doud received that they were doing an investigation of Cardinal Health and he was later notified by letter about this investigation.

MR. GOTTLIEB: I understand what your Honor is saying. As a matter of rule of evidence, the only thing is the witness who would introduce this email can then read this, however it's going to be done. But to call the investigator to go and testify about something when she never discussed it with Larry Doud, she wasn't responsible for sending the email, it is the wrong witness. She is not a competent witness to testify about the underlying facts.

THE COURT: You have to tell me one final time what is it that you want her to say in that context?

MS. ROTHMAN: Ms. Carter is going to explain that in 2012, she was involved in a DEA investigation, an action against Cardinal Health, that Cardinal Health was sending excessive amounts of oxycodone to pharmacies in Florida; that Cardinal Health failed to report suspicious orders and failed maintain effective control against diversion, all of which is in this article, your Honor.

She'll talk a little bit about the things she did in

Florida, and then she's going to explain the disposition of the case against Cardinal Health. That's it.

THE COURT: What is always not useful is to tell me what the witness is going to talk about. What I want to know is what the witness is going to say. What is she going to say about her investigation and what is she going to say about its conclusion.

MS. ROTHMAN: She was the team leader in the Lakeland Florida in connection with the Cardinal Health. The DEA learned that Cardinal Health was shipping excessive quantities of oxycodone to several pharmacies Lakeland, Florida. They filed an order to show cause for immediate suspicion of Cardinal Health's license, and that the allegations against Cardinal Health were for failing to report suspicious orders, failing to maintain effective control against diversion, and that the case was resolved with a settlement between Cardinal Health and the DEA.

THE COURT: And in what part of that information is there going to be testimony that Mr. Doud was --

MS. ROTHMAN: Ms. Carter doesn't know Mr. Doud. She's going to say nothing about Mr. Doud. Mr. Doud did receive this email, and the substance of her testimony is contained within this email, except for the settlement, because time wise the settlement hadn't happened yet. So this is simply to help the jury understand --

THE COURT: What are you trying to prove by this email?

MS. ROTHMAN: It's putting the defendant on knowledge of his responsibilities as a wholesale distributor to maintain effective controls against diversion, that the DEA was looking at companies like RDC to ensure they were complying with those obligations. And yet despite knowing that, he still decided to engage in the charged conspiracy. That's the point of the article.

MR. GOTTLIEB: Your Honor, to actually have a witness talk about, I investigated, there was a settlement in that case, putting this before this jury is something that is totally irrelevant to Mr. Doud and the charges in this case. With all due respect, again, the email --

THE COURT: Everything you say is with all due respect.

MS. ROTHMAN: Quite hyperbole.

MR. GOTTLIEB: You never know. Now that we heard what the offer of proof is, it would be inappropriate to talk about some other company wound up being fined.

THE COURT: She can testify that she conducted an investigation of that company. Period. Now if it's another witness who's going to say they notified things to him and you want to demonstrate that that had put him on notice of what this company had done, then you can do that. But at this point

at least premature if not inadmissible, to have her start testifying about the results of an investigation that did not involve him.

MS. ROTHMAN: Your Honor, would it be acceptable to the Court to not talk about the settlement but to talk about the allegations in the case.

THE COURT: Sure. If it's consistent. She can say, I did this investigation of this company where we investigated and they did X, Y, Z. I assume at some point it's going to come out that -- I didn't look at the full document. It's going to come out that he was notified about this and whether or not that other person -- and it becomes relevant -- can say what the result of the investigation is.

But the question is not what the result of the investigation is, the question is what was he put on notice about and what was his responsibility once he was put on notice. And whether or not they robbed the bank after he was put on notice is not particularly telling one way or the other. The way to prove this case is not to prove that they warned him about something and then somebody else was found guilty of something. It's about what he had notice of.

And it becomes relevant to go into the details of these investigations and the conclusion of these investigations, that's fine. But the conclusion of investigations don't, in fact, prove anything with regard to

his knowledge. What proves -- in regard to his knowledge, is that people say he was notified and what he did and didn't do having been put on notice. And, in fact, even if they were found not to have violated the regulations, it would not effect the determination of whether or not he properly met his legal obligations when he was provided with this.

MR. JANEY: The document, this exhibit, can't come in.

MS. ROTHMAN: I'm not offering this exhibit.

THE COURT: Unless you want to deal with it now. You can anticipate it's probably going to come in through the person that lays the proper foundation.

(In open court)

MS. ROTHMAN: May I proceed, your Honor.

THE COURT: Yes.

BY MS. ROTHMAN:

Q. We were talking about the Cardinal Health case, can you provide some background on what that investigation was?

A. That investigation was regarding Cardinal Health. Cardinal Health failed to maintain effective controls against diversion of controlled substances in 2012 at its Lakeland, Florida facility. The DEA issued an immediate suspension order and order to show cause against Cardinal Health.

Q. What type of business is Cardinal Health?

A. Cardinal Health is a wholesale distributor.

Q. And the nature of the allegations against Cardinal Health were what again?

MR. GOTTLIEB: Your Honor, objection.

THE COURT: Sustained. Asked and answered.

Q. What was your involvement in that investigation, Ms. Carter?

A. I was the team leader. I was detailed from Seattle. I was in Seattle at the time as a supervisor. I was detailed to Florida to lead the team to conduct this investigation.

Q. What does it mean to be a team leader? What did you do?

A. I coordinated all of the activities and the investigation.

Q. Thank you, Ms. Carter. Let me ask you this: If the DEA

had known that a distributor's practice was not to report suspicious orders, what would the DEA do?

A. Well, if the DEA knows that a distributor is not reporting suspicious orders, the DEA would take action, such as the action that was taken against Cardinal Health. They would issue an order to show cause and potentially an immediate suspension order, depending on the circumstances against that distributor.

MS. ROTHMAN: Your Honor, may I have one moment.

THE COURT: Yes.

MS. ROTHMAN: Your Honor, I have no further questions for Ms. Carter.

THE COURT: Did you have questions for this witness?

MR. GOTTLIEB: Yes, your Honor.

CROSS-EXAMINATION

BY MR. GOTTLIEB:

Q. Ms. Carter, good afternoon.

A. Good afternoon.

Q. Let me just start by what you were just asked about with regard to Cardinal Health. Is it fair to say that investigation did not involve RDC?

A. Can you repeat that. I'm having a hard time understanding.

Q. Is it fair to say that the Cardinal Health investigation had nothing to do with RDC?

A. Yes, RDC had nothing to do with Cardinal Health.

Q. Is it fair to say that the RDC -- withdrawn.
Is it fair to say that the Cardinal Health investigation had nothing to do with Larry Doud?
A. As far as I know, yes, it's fair to say that.
Q. Well, you were the lead investigator, correct?
A. Yes, the team leader.
Q. And as the team leader, you would know whether or not it involved Larry Doud, correct?
A. As far as I know, it did not, yes.
Q. Now, with regard to this case, you were not asked to undertake an investigation of RDC, correct?
A. That's correct.
Q. You had no dealings with RDC, correct?
A. That's correct.
Q. You had no dealings or conversations with Larry Doud, correct?
A. That's correct.
Q. You've never spoken to him, correct?
A. I have not.
Q. Now, have you worked at DEA for a long time, that's somewhat 31 years, correct?
A. Yes, almost 31 years.
Q. And you've done a lot of traveling over those years, haven't you?
A. I did, yes.

Q. Is it fair to say that through your knowledge and your experience, you have a good idea of what the law specifically says with regard to the issue for this jury that concerns diversion, correct?

MS. ROTHMAN: Objection.

THE COURT: I'm going to sustain as to the form of the question.

Q. You have a lot of experience in training with regard to the law as it pertains to controlled substance diversion, correct?

A. Yes.

Q. And you testified about the rules and regulations that the law, henceforth, concerning compliance programs and efforts to stem diversion, correct?

A. Yeah, I testified about certain regulations involving the compliance programs, yes.

Q. Now, you mentioned on direct examination the CFR, the Code of Federal Regulations, correct?

A. Yes.

Q. And what is that?

A. The Code of Federal Regulations are the implementing regulations that were derived from the Controlled Substances Act, so it's the federal regulations.

Q. And when you say it's a regulation, it's not a criminal statute, it's not criminal law, correct?

MS. ROTHMAN: Objection, your Honor.

THE COURT: Overruled. You can answer.

A. The regulations, again, they're the implementing regulations. They're not the CSA, yes. Is that what you're asking me?

Q. No. Thank you. So the CSA, that's the Controlled Substances Act, correct?

A. Yes.

Q. That was passed, I guess, by Congress, correct?

A. Yes.

Q. And that is a criminal statute, correct?

A. There are criminal statutes in it, yes.

Q. Now, the Code of Federal Regulations, that's not a criminal statute, correct?

A. No, it's the implementing regulations.

Q. And it's the implementing regulations pertaining to the DEA and the requirements that registrants have in part to stem diversion, correct?

A. It's the regulations that the registrants have to follow in order to comply with keeping their registration, yes.

Q. In order to keep the DEA registration, the CFR, the Code of Federal Regulations lays out what's required, correct?

A. Yes.

Q. You would agree that a violation of the CFR does not in and of itself mean that you are committing a crime, correct?

A. Well, that's not necessarily correct because the

regulations all are derived from the Controlled Substances Act, so they do stem back to certain provisions under the Controlled Substances Act, under different portions of the Controlled Substances act.

Q. The question is, though, can we agree that a violation of the CFR, the Code of Federal Regulations, does not in and of itself mean that the person or registrant has committed a crime?

MS. ROTHMAN: Objection.

THE COURT: Overruled. She can answer.

A. Again, it depends on the regulation because some of the regulations -- yes, if they fail to report suspicious orders, then they're failing to file a record that's required to be kept, which means they have violated the federal law, yes. They violated the federal law under 842 and 21 U.S.C. 842 and 21 U.S.C. 843.

Q. When you say the law, you're talking about the aspects of the Controlled Substances Act, correct?

A. Yes.

Q. Would you agree that the DEA regulations in the CFR codify the responsibilities that distributors and others must adhere to when dealing with controlled substances?

A. Is that a question?

Q. Yes.

A. Okay. It did codify what the distributors had to adhere

to, yes, and others.

MR. GOTTLIEB: Can we put up, and I would ask that the Court take judicial notice of the two CFR regulations that were referred to. Specifically if I can show the witness.

THE COURT: You want to show the witness or you want this in evidence?

MR. GOTTLIEB: I'll show the witness and your Honor will also be able to see Defendant's L9 and Defendant's L10.

THE COURT: I see something in a little box. I see it, but I cannot read it.

MR. GOTTLIEB: It's like really small or something.

THE COURT: Yes. Okay. Go ahead.

MR. GOTTLIEB: Your Honor, I'm going to ask that Defendant's L9 -- that your Honor take judicial notice of 21 CFR 1301.71.

THE COURT: And you're offering that exhibit in evidence?

MR. GOTTLIEB: Yes.

THE COURT: Any objection?

MS. ROTHMAN: Your Honor, relevance.

MR. GOTTLIEB: The relevance is that the witness has made reference to the CFR and the provisions that pertain directly to a registrant's obligations and responsibilities.

THE COURT: You have any questions with regard to these particular regulations of this witness?

MR. GOTTLIEB: I will, your Honor.

THE COURT: Why don't you lay somewhat of a foundation for its relevance and then I can decide whether I should take judicial notice.

BY MR. GOTTLIEB:

Q. Ms. Carter, do you see 21, CFR 1301.71?

A. Yes.

Q. And what is that, please?

A. That's the section of this particular -- part of the CFR? Is that what you're asking me?

Q. What's this regulation about? What does it pertain to?

A. It's entitled security requirements generally.

Q. Ms. Carter, doesn't it pertain to registrants being required to have effective controls and procedures to guard against theft and diversion of controlled substances, the first sentence, Ms. Carter?

A. You want me to read the first sentence?

Q. If you can just look at it. Doesn't this regulation of the CFR pertain to the very issue we're talking about that you've been testifying about?

A. This does in part refer -- discuss what I was talking about, but I think we were referring to the 21 CFR 823(e).

Q. Let's just take this one. It's marked for identification. This pertains in part to the requirements in the CFR concerning procedures to guard against diversion of controlled substances,

correct?

A. That is what this states here, yes.

Q. Well, you have seen this regulation before, haven't you?

A. I have.

MR. GOTTLIEB: Your Honor, I ask that this be received in evidence because this is one of the regulations that's already been testified to.

MS. ROTHMAN: Objection, relevance, your Honor.

THE COURT: Overruled. I admit it into evidence. Let's move forward.

MR. GOTTLIEB: Your Honor, can this be shown to the jury. Is it shown to the jury.

THE COURT: Yes.

MR. GOTTLIEB: If we could highlight that first paragraph small case A. Thank you.

Q. This section of the CFR indicates that all applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances, correct?

A. Yes, that's what it states.

(Continued on next page)

Q. We can move up to the second subparagraph, paragraph which is lowercase (b). And 1301.71(b), this section of this regulation deals with substantial compliance with the standards set forth in 1301.72, 1301.76 may be deemed sufficient by

administrator after evaluation of the overall security system and needs of the applicant or registrant, correct?

A. Yes, that's what it states.

MS. ROTHMAN: Your Honor, I think we need a sidebar. I'm sorry.

THE COURT: Come up.

(Continued on next page)

(At the sidebar)

MS. ROTHMAN: I don't want to interrupt Mr. Gottlieb's cross-examination. I think there is a real problem with introducing statutory text for the jury. The Court can instruct the jury on what the law is. I think there is confusion here that the jury is going to read in this and form their own opinion about what the law requires, whether the defendant has violated the law. Just as an example, substantial compliance within the standards set forth in 1301.72 and 76, none of which the defendant is offering, may be deemed sufficient by the administrator. That's extremely confusing, suggesting that substantial compliance with -- let me finish. Substantial compliance with whatever obligations means that a distributor or the defendant is following the law.

I think the Court needs to tell the jury, if your Honor is going to allow this to continue, that the Court will tell the jury what the law is, the instructions they should follow in determining the questions of the defendant's guilt, and not some language in a statute, CFR, the defense has decided to put into evidence.

That's the government's objection.

MR. GOTTLIEB: Your Honor, as a basic fundamental rule, judicial notice can always be taken of a statute. I am not going to be asking her to evaluate this.

THE COURT: That's not the relevance issue. That's my

issue. It has nothing to do with taking judicial notice. I can't take judicial notice of information that's not relevant to the case. So what are you going to do with it? Is she correct that you simply want to argue that because of the general language in the regulations, that it doesn't violate the criminal law?

MR. GOTTLIEB: No. That's not what I'm saying. She referenced on her direct that the Code of Federal Regulations requires a steps to prevent diversion. I am now on cross-examination pointing out what she is referring to. The government would simply like this general notion the law requires diversion, when the jury is entitled, we are entitled to lay the foundation as to what is in the law and what is not in the law.

THE COURT: Well, I'm not sure you are entitled to do that. You are not entitled to argue to the jury what you say is the law and what is not in the law. In this case, I will give you some leeway, if you get to the point of relevant questions about whether or not the Code of Federal Regulations and/or the statute requires he follows certain procedures.

It seems to me that the government is right, that it doesn't give you the ability to argue that, oh, well, you can't convict him if he followed the code of regulations but violated the federal statute.

MR. GOTTLIEB: I am not saying that, your Honor.

THE COURT: That's her concern. That you want to imply that to the jury. Look, she testified about rules and regulations that he has to follow. If you want, if you want to ask her some questions about that, that's fine and dandy. If you're getting particularly close, I don't think you've crossed the line yet of instructing the jury that if he complied with this exhibit, therefore he's not guilty. The government has the full opportunity to go back on redirect, if you wish, and have this witness say what she has already said, that this is part of what he has to do, among other things. He has to do some other things. And that's why I sustained the objection with regard to whether or not it was about the issue before this jury. It's not about the issue before this jury. The jury is not supposed to decide whether or not he violated the Code of Federal Regulations. This jury is supposed to decide whether or not he violated the conspiracy statute. That's where we're going.

I will give you some leeway in this regard. We are not going to go a whole lot further. I'll give you some opportunity to argue that somehow he's not guilty of the crimes with which he is charged because of some interpretation of the Code of Federal Regulations.

MS. ROTHMAN: The whole premise of this being a civil versus criminal violation is entirely inappropriate in this case. This is a criminal trial. The defendant is charged with

federal criminal violations, crimes your Honor will instruct the jury on the law. Any suggestion this is really a civil thing is entirely inappropriate.

THE COURT: I haven't addressed that because I haven't gotten any objection to that argument or those issues to this point.

MR. GOTTLIEB: Your Honor --

THE COURT: You know what her concern is.

MR. GOTTLIEB: I do.

THE COURT: She is afraid of where you are going. Don't go there.

MR. GOTTLIEB: I want your Honor to understand when the witness says the law required to set up a diversion program, the law is required to do this. That's her direct testimony. I certainly should be entitled to say, okay, what law are you talking about?

THE COURT: You didn't say that. You didn't say what law are you talking about. You showed this exhibit in front of her and you want to say that this is what controls here, and it's not what controls here. We all know that. It's not what controls here.

I'll give you some leeway, but I will anticipate, if I think you crossed that line, giving the jury specific instruction that he's not on trial or any violation of the Code of Federal Regulations. He is on trial for violating criminal

statutes, and that's their determination to make, and it is not a determination of any other witness or lawyer to argue that simply because they want to argue that the code of regulations says a certain thing, that means that you must be necessarily not guilty.

MR. GOTTLIEB: That's not remotely what I intend to argue. I simply want the jury to know when she says the law requires diversion, this is the law.

THE COURT: No, it's not the only law. See, that's the thing. That is not giving the jury an accurate portrayal of what the law requires. That requires certain things and the criminal law requires certain other things.

MS. ROTHMAN: Your Honor --

THE COURT: It is not the same. And no, you shouldn't go that way to try to imply to the jury that what controls here is the Code of Federal Regulations. It doesn't.

MR. GOTTLIEB: Your Honor --

THE COURT: You couldn't make this argument if he was a street drug dealer and you wanted to say, well, that isn't required by the Code of Federal Regulations.

MR. GOTTLIEB: Think about it. The government on direct puts in two guidance letters. If you violate the guidance letters, that's certainly not in and of itself a crime. I have to be able to cross-examine to put it in perspective.

THE COURT: You know this witness will not say, nor will any witness say, that simply because the defendant complies with this code of regulation, that he can't be guilty of a conspiracy to distribute or a conspiracy to defraud the DEA.

MR. GOTTLIEB: I wouldn't expect her to say that. I am not saying that, Judge.

THE COURT: I'm not sure where else you are going by the nature of what you're trying to establish.

MR. GOTTLIEB: Okay. Just so you know, the next one is specifically the CFR that she mentioned, which talks about the diversion. I'm asking for judicial notice of that and I am moving on.

MS. ROTHMAN: I don't know why we are allowing defense to be arguing what the law is to the jury. It is the Court's job to instruct on the law. The Court will do that at the end. The letters were offered because they were sent to the defendant's company. In fact, there will be testimony they were sent to the defendant, and what he chose to do and didn't do is directly relevant to the charges in this case. This is pure grounds for confusing the jury and suggesting --

MR. GOTTLIEB: Your Honor, we just sat here for over an hour with the witness instructing or being asked about what the law says. We sat here with her saying the law requires this, the law requires this, the law requires this. How can we

not be entitled to say, okay, what law are you talking about?

THE COURT: That's not what you are asking.

MR. GOTTLIEB: Because that's what -- that is what she is referring to. We know.

THE COURT: I will give you some leeway. I'll let you walk this line. But I am going to shut you down real quick if I think that you ask her any question that implies that argument. And I am going to consider strongly giving the jury, either now or later, an instruction that I will instruct them on the law and the lawyers don't instruct them on the law and the Code of Federal Regulations is not the controlling law with regard to what they have to decide as to whether or not he violated the law.

MR. GOTTLIEB: Thank you.

(Continued on next page)

(In open court)

THE COURT: Continue, Mr. Gottlieb.

MR. GOTTLIEB: Thank you. If we can put on the screen for identification, your Honor, Defendant's L10.

Q. Now, Ms. Carter, on direct examination, you referenced 21 CFR 1301.74. Is it fair to say that that section talks and addresses the issue in the Code of Federal Regulations regarding a requirement that a registrant design and operate a system to disclose to the registrant suspicious orders of controlled substances? Just yes or no?

A. Yes, 1301.74(b), yes.

Q. And that was the section of the law that you referred to on direct, correct?

A. Yes, I think it was in the letter.

Q. Yes.

MR. GOTTLIEB: I would ask that this as well as L9, both documents be received in evidence.

THE COURT: I'll admit those documents in evidence.

(Defendant's Exhibit L9 and L10 received in evidence)

MR. GOTTLIEB: Thank you. If we can just look at L10 and if we can show it to the jury. If we can highlight (b).

Q. This section indicates "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the field division office of the administration in his area of

suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

Correct?

A. Yes.

Q. Thank you. You would agree, I think, that the mission of the DEA diversion control is to investigate DEA registrants with the aim of preventing diversion of controlled substances?

A. That's part of the mission, yes.

Q. Part of that mission is also to ensure an adequate uninterrupted supply of controlled substance for legitimate medical, commercial, and scientific needs, correct?

A. Yes.

Q. I'm sure we can agree there are millions of people who need and require legitimately pain medications.

A. Yeah, I mean, it's -- I don't know the number of people that require them.

Q. You would agree there are a lot of people who require medications following an operation, chronic pain, and for a host of other legitimate medical reasons, correct?

A. Yes. There are a lot of -- a lot of people that require them for legitimate medical purpose.

Q. Can we also agree that distributors play an important role, a vital role in ensuring that pharmacies have sufficient

supplies of drugs --

MS. ROTHMAN: Objection.

Q. -- to fulfill patients' legitimate medical needs?

MS. ROTHMAN: Objection.

THE COURT: I'm going to sustain the objection.

Q. You were asked on direct examination whether or not it's legal or illegal to have a business of distributing controlled substances. Correct?

MS. ROTHMAN: Objection.

THE COURT: Overruled. You can answer.

A. Can you repeat that?

Q. Is it legal for a company to be in the business to distribute controlled substances; yes or no?

A. It's legal if they're registered by the DEA. They have to have a DEA registration to do so, yes.

Q. Would you agree that the vast majority of prescribers, doctors, are trying to do the right thing, based on your experience over the years?

MS. ROTHMAN: Objection.

THE COURT: Sustained.

Q. Well, not all doctors or pharmacies are committing crimes if they prescribe or sell controlled substances, correct?

A. No, not -- I mean, no.

Q. While you were working at DEA for quite a long time, you told us, I believe you said about 2000 or so, that oxycodone

exploded in America. Is that fair to say? An epidemic of oxycodone?

A. I said there was an epidemic in -- starting in the late '90s into the early 2000s, yes.

MR. GOTTLIEB: Can we put up on the board, your Honor, Government's Exhibit 901 which was received in evidence.

THE COURT: Yes.

Q. I think everyone has it. This was the diagram of I think you said it was the chain of supply, correct?

A. Registrants in the supply chain, yes.

Q. Now, this starts with the manufacturer of the controlled substances and goes all the way to the medical provider, correct?

A. Yes.

Q. But the DEA is also part of the supply chain and plays a role in setting the supply, doesn't it?

A. DEA is not part of the supply chain, no.

Q. Does the DEA play any role in deciding how much controlled substances are available for distribution?

A. Are you asking me if the DEA sets a quota?

Q. I didn't ask that, but that will be my question now.

The DEA sets a quota of how much controlled substances can be manufactured and put into the supply chain, correct?

A. The DEA is tasked with -- yes, the DEA is required to do that, yes.

Q. And the way the amount of controlled substances that can be placed and are placed in the marketplace for people to obtain is determined by specific quotas that the DEA is required to set pursuant to law. Correct?

A. The -- can you repeat the first part of that again?

Q. The amount of controlled substances, the way that it's determined, the amount that can be placed in the marketplace for people to obtain pain medications and other controlled substances, is determined by quotas that the DEA is required to set under the Controlled Substances Act, correct?

A. No, I don't think that that's a correct statement.

Q. Do you know what an annual production quota is?

A. I do.

Q. What's an annual production quota?

A. That's the amount of aggregate production quota is the term, and it is the amount that a specific manufacturer's authorized to produce.

Q. Who makes the decision as to how much the manufacturer is authorized to produce?

A. Well, the DEA makes the decision, but the decision is based upon the projected estimated medical need that was submitted to them by the manufacturer.

Q. So all I asked you, the DEA makes the decision, correct?

A. The DEA does make the decision, yes.

Q. The DEA makes the decision based on a number of factors, on

how much to put into our marketplace for distribution and use, correct?

A. The DEA sets the quota based upon the estimated medical need.

Q. And the way they set this estimated need, do they go out and do their own investigation, do they count -- how do they go about determining what the quota should be?

A. The manufacturers submit the information to the DEA.

Q. So the DEA makes the first decision as to how much controlled substances to put in the marketplace by going to the manufacturers and getting their data?

MS. ROTHMAN: Objection, relevance.

THE COURT: Overruled. You can answer that.

A. The DEA doesn't go to the manufacturers to seek the information. The manufacturer comes to the DEA to request to produce the drugs.

Q. Would you agree then that from 2010 to 2016, the DEA routinely increased production quotas for opioids by substantial amounts?

MS. ROTHMAN: Objection, your Honor.

THE COURT: I'm going to sustain this. I'm not sure I see the relevance.

Q. Well, when the DEA makes its decision, they rely on data that they receive from, you said, manufacturers, correct?

MS. ROTHMAN: Objection.

THE COURT: Overruled. You can answer.

A. Yes, as the manufacturers make the request, and they provide the data.

Q. And the DEA is assuming that the data that they are receiving from manufacturers is truthful, correct?

A. The DEA has to go upon the assumption that the information provided is factual, yes.

Q. And would you agree that the DEA, in deciding to increase the amount of opioids into our marketplace, if the manufacturer is lying, or falsifying the data, is making an important decision based on false information?

MS. ROTHMAN: Objection.

THE COURT: Sustained. I'm not sure where you are going with this, Mr. Gottlieb.

MR. GOTTLIEB: I'll rephrase it, your Honor.

THE COURT: Okay.

Q. The DEA as the decision maker in how much controlled substances can be placed in the marketplace, they are relying on accurate, what they hope is accurate data, correct?

MS. ROTHMAN: Objection.

THE COURT: Sustained. Asked and answered I believe.

Q. Just between then 2010-2016, would you agree that the amount authorized to be distributed increased each year?

MS. ROTHMAN: Objection.

THE COURT: I'll let her answer that.

A. I would have to see the numbers. I don't know off the top of my head whether, when the quota was increased and when it was decreased.

Q. As you sit here today, you can't say that the DEA that you were working for at this time that I'm referring to, you are not able to say one way or the other whether or not the production quota increased each year?

MS. ROTHMAN: Objection.

THE COURT: Overruled. You can answer.

A. Again, you would have to show me the numbers because I don't know the years of what the quotas were each year.

Q. You are aware of the attorney general's investigation of West Virginia that investigated the DEA during the time you were there showing the failures of the DEA to account for diversion, aren't you?

MS. ROTHMAN: Objection, your Honor. Relevance.

THE COURT: I'm going to sustain the objection. We're going to take a break, Mr. Gottlieb.

Ladies and gentlemen, don't discuss the case, keep an open mind. We'll take a 10-minute break and I'll bring you back in and we can continue.

(Jury excused)

(Continued on next page)

(In open court)

THE COURT: Let me address my issue first so we can save some time.

Mr. Gottlieb, it is not clear to me what you are blaming the DEA for that has any relevance to whether or not your client distributed drugs or defrauded the DEA. You can blame them for the --

MR. GOTTLIEB: I was waiting.

THE COURT: Sure, I'm sorry.

It seems to me you want to blame them for the increase in opioid use, but I don't see any relevance whatsoever how it makes your client more or less likely that he violated --

MR. GOTTLIEB: I agree 1,000 percent with your Honor.

THE COURT: Why don't you stop asking those questions?

MR. GOTTLIEB: No, no, I'll tell you why. Because my client, Mr. Doud, is being accused of a criminal violation.

THE COURT: Right.

MR. GOTTLIEB: When investigations are done, Linden Care and all of these pharmacists and reporting are coming back that they are in compliance, and he's getting information from this investigator, this consultant, he's getting this information from the owners of Linden Care that everything is okay. We start off there. That certainly affects his intent.

THE COURT: That's an interesting argument that has absolutely nothing to do with the questions you just asked her.

MR. GOTTLIEB: No, but if I can, let me try to connect it. The DEA, which is primarily responsible in selling and getting opioids out in the market, much more than RDC or Mr. Doud, the DEA --

THE COURT: I am not sure about that. But go ahead.

MR. GOTTLIEB: Well, but, they also are going through the same process that the evidence is going to show that Mr. Doud and RDC went through. They relied on the same process. If the --

THE COURT: So what? What they did or didn't do with regard to their investigations, how does that make him more or less likely that he violated the criminal conspiracy law?

MR. GOTTLIEB: Because, the fact of the matter is he's being charged with criminal conspiracy.

THE COURT: Right.

MR. GOTTLIEB: Based on ignoring red flags.

THE COURT: Right.

MR. GOTTLIEB: The DEA also is aware of red flags, yet during this entire period of time, the DEA is relying on information it's receiving and increasing in making --

THE COURT: That's an interesting argument that I just heard for the first time. Because that's not what you've asked her. You didn't ask her anything like that. You wanted to know whether or not there was an increase in the number of opioids that were being manufactured, and whether or not the

DEA was responsible for that increase. Those questions have absolutely nothing to do with the charges in this case.

MR. GOTTLIEB: I was merely laying the foundation --

THE COURT: Your foundational questions weren't relevant.

MR. GOTTLIEB: Okay. But, the point is, your Honor, I was at that question just now, about you relied on the data that's being handed to you.

THE COURT: And she said "yes."

MR. GOTTLIEB: An important decision, and then there was an objection. I'm ready to move on.

THE COURT: That's fine and dandy saying you are ready to move on. I am trying to get some guidance for the future. And I don't see it is a relevant inquiry as to whether or not they relied on information that was provided to them by manufacturers in setting the amount of opioids that were being produced by that manufacturer. That scenario has nothing to do with what the government is accusing your client of doing. That's not what the government is accusing your client of doing. The government is accusing your client of not meeting his obligations as a registrant, and for knowingly agreeing to provide drugs when he knew that they were not being appropriately prescribed and failing to give accurate information, agreeing to give inaccurate information, and withhold information from the DEA.

That has nothing to do with the questions just asked.

MR. GOTTLIEB: But your Honor, just so you can understand where we are. That's the government's argument.

THE COURT: What's the government's argument?

MR. GOTTLIEB: The government's argument is he ignored.

THE COURT: Right. And that's the only issue for this jury, isn't it?

MR. GOTTLIEB: But, the reason for these questions is that everybody in the chain, everybody in this type of work, must rely and does rely on information.

THE COURT: Right.

MR. GOTTLIEB: Because the evidence --

THE COURT: And nobody disagrees with that. Nobody in this room disagrees that to do this job appropriately, you have to rely on accurate information being given to you.

But, the issue here is that you're given the accurate information and you know that people are not distributing drugs properly, what independent obligations do you have. That's what the issue is. The issue is not trying to figure out who relied on who. The government has no evidence that they're offering that your client relied on some information that he got from somebody else. They're making exactly the opposite argument, and they're presenting exactly the opposite proof that they said that they are going to offer proof that your

client was fully aware of what the accurate information was, and he misused that information.

MR. GOTTLIEB: But your Honor, what you are in effect saying, if the government says they have proof contrary to what I am saying, that's what then determines what I can then go into? Because the proof in this case will be the government is wrong.

THE COURT: No, no, no.

MR. GOTTLIEB: The proof in this case is he did have information that things were okay, and that's why certain decisions were made, which then --

THE COURT: Mr. Gottlieb, if you can make a logical argument that I can follow, then I will give you some leeway on that. But that's not what you are asking this witness of and it is, even to that argument, it is totally irrelevant what the DEA did. Even if the DEA sat on their hands and did nothing, that is totally irrelevant to the issue before this jury. Whether they relied on accurate information or inaccurate information is totally irrelevant to the issues before this jury.

And I've given you some leeway to ask these questions, but these questions are not appropriate foundation to argue that because the DEA relied on manufacturers' estimates of what the opioid manufacture should be, that somehow that means that your client must have done the same thing.

MR. GOTTLIEB: Well, but it also, your Honor, goes to the government puts on a witness, who is being very self-righteous and she's done everything else.

THE COURT: She has the right to be self-righteous.

MR. GOTTLIEB: I have the right to question her about what she did and what she relied on.

THE COURT: You don't get to just spank her. You have to have a legitimate basis for the substance of the information you are trying to elicit from her.

Are you just trying to show she is a bad person? Is this impeachment?

MR. GOTTLIEB: Yes, it is impeachment.

THE COURT: Of this witness?

MR. GOTTLIEB: It is impeachment.

THE COURT: Of this witness?

MR. GOTTLIEB: To put it in perspective. To make it something that's different, and, your Honor, frankly, that's even why the law is important, because she and the government is very careful to simply have her say the law required this, the law required that. Well, we are entitled to say where the heck in the law does it explain in detail what a suspicious order is? I know what the answer is. There is nothing beyond what your Honor has already seen.

THE COURT: That's an interesting argument. It is not the nature of the questions you've been asking this witness.

You haven't asked this witness that.

MR. GOTTLIEB: I just started. I just started.

THE COURT: No, you didn't just start. You are asking questions about whether or not she has -- not even her. That the DEA has to rely on the manufacturers' estimates. What are you going to argue from that? That advances your argument how? I still don't understand.

MR. GOTTLIEB: She's testifying as somebody from the DEA, as an authority on the DEA.

THE COURT: No, she's not testifying that way. You've already argued at sidebar she is not an expert witness. That's not what she's testifying to.

MR. GOTTLIEB: I ask that her entire testimony be stricken. Because she got up there and testified for the jury what the law is, what it requires.

THE COURT: She didn't say anything about whether or not the DEA was doing their job the proper way. And that's what you want to inquire, and that's what you inquired about, and that's totally irrelevant to the issues here, about how great a job the DEA is doing. The DEA could have been doing the lousiest job, but that doesn't affect whether or not your client is guilty of the charges that he's been charged with. And to simply just want to throw mud at the DEA or say, well, they are doing such a bad job, you should acquit my client, and quite frankly, I am not even sure you have even established

that they are doing a bad job.

MR. GOTTLIEB: That's not our argument. It is not our position and it never has been our position.

THE COURT: That's the best I can do in trying to articulate what it is that you have been asking this witness. Because I just don't understand where you are going with this. Other than just to try to throw mud at the DEA.

I gave you some leeway with regard to that, but we are not going to go down that route of spending significant time trying to figure out whether or not the DEA had to rely on the manufacturers in determining how much opioids should be out there. And the implication that you want that the jury to draw that it is their fault --

MR. GOTTLIEB: No.

THE COURT: -- because they increased the number of opioids out there. Or I don't know. I shouldn't try to make your argument for you, because it is as close as I can come. It makes absolutely no sense. And you want to acknowledge it makes no sense. So I still don't know what the purpose is.

MR. GOTTLIEB: As the way your Honor has presented it, it makes no sense. But it's on me. That makes no sense because that's not our position.

THE COURT: Let me hear from the government. I don't want to debate it with you.

MS. ROTHMAN: I think your Honor zoomed in on the

issue here. The DEA is not on trial. What the DEA did or didn't do is not a question for the jury. There is one question: Whether the defendant committed the crimes he's charged with.

The suggestions by the defense that the DEA increased the quotas or didn't do this are improper, they're confusing. I will object, your Honor. I would ask that Mr. Gottlieb stop asking those questions. I will continue to object. And I would ask that your Court sustain any objections because it is simply improper.

THE COURT: Well, it is as close as I can come to allowing you some leeway. I have overruled half of the government's objections. But, I don't see any other direction that you've been going, other than the direction that I believe is not a proper subject of cross-examination.

So, if you want to take explain to us what you are going to ask next, if we can resolve that, or you can just abandon this area. But if you want to tell me what else you want her to say, and tell me why that's relevant to this case, then articulate it now, because otherwise I am going to shut this down.

MR. GOTTLIEB: I'm moving on.

MR. ROOS: Your Honor, on a unrelated subject. I see it's 3:45. Is your Honor going to go until 5 or 5:30?

THE COURT: 5.

How long were you going to go, Mr. Gottlieb?

MR. GOTTLIEB: Not a lot but there is some, Judge.

THE COURT: Can I get a better estimate in terms of numbers?

MR. GOTTLIEB: If we start at 4, I would hope to be done by 4:30.

THE COURT: Okay. That's a good estimate.

MR. GOTTLIEB: Without objections, I can probably accomplish that.

THE COURT: We'll see if you can ask some questions that won't get objected to.

MR. ROOS: I think we told the Court earlier it was going to be Carter, then Masseth, then Castro. It is possible we switch those two witnesses.

THE COURT: It's up to you. If we finish this witness before 4:30, you can be confident we can put at least another half hour worth of testimony. If it goes much beyond that, then maybe we might adjourn.

MR. ROOS: The other thing, your Honor, is the parties have some stipulations. Some of the stipulations are just to admit certain exhibits. Is it okay with your Honor if I just read portions of it?

THE COURT: Yes.

MR. ROOS: And then offer it and not bother with reading the entire thing?

THE COURT: That's fine with me. You can do it any time you wish to do that. Just mark it as an exhibit if you have a written stipulation, and you can offer.

MR. GOTTLIEB: As long as it's vice versa. I have absolutely no objection.

MR. ROOS: I know nobody loves the lengthy reading. I am looking at it, and it seems to number a few pages, so it would be helpful to everyone.

THE COURT: Let's take another five minutes and let's continue and let's focus.

(Recess)

(Continued on next page)

(Jury present)

THE COURT: Mr. Gottlieb.

MR. GOTTLIEB: Thank you.

BY MR. GOTTLIEB:

Q. Ms. Carter, we left off and you testified on direct about suspicious orders and what they are. Do you recall that?

A. Yes.

Q. And can you tell us what statute actually defines a suspicious order?

A. So suspicious orders are defined under the regulation that we were looking at earlier, 1304.21(b) I believe. But, maybe it's 7 -- the one we were looking at right before the break.

Q. And without putting it up on the screen, what you're referring to is in that CFR, it reads: Suspicious order include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequencies.

Correct?

A. Yes.

Q. There is no further explanation of what a suspicious order is, correct?

A. That's -- that's what's written in the CFR, yes.

Q. Is there any other statute that lays out specifically more information about what a suspicious order is; yes or no?

A. No, that's the -- that's the regulation that defines in general terms what a suspicious order is, yes.

Q. Is it fair to say there is no further definition of unusual frequency?

A. The regulation doesn't define unusual frequency.

Q. Using the term unusual frequency, do you know of any statute that actually defines what unusual frequency even means?

A. No, there is no regulation that is defining what unusual frequency is.

Q. Is there any regulation that defines what it means to deviate substantially from a normal pattern?

A. No.

Q. Is there any regulation that quantifies what the line is between usual and unusual orders?

A. No.

Q. You gave this jury a list of potential red flags and I'd like to just briefly go through them with you.

You talked about the amount of controlled substances versus non-controlled substances, correct?

A. The percentage, yes, the difference percentage I should say.

Q. Would you agree --

THE COURT: Excuse me. Just could you point the microphone closer to you, please. Toward your mouth. That's good. Thank you.

THE WITNESS: Okay. Is that better?

THE COURT: Much better.

Q. Would you agree, Ms. Carter, that the amount of controlled substances ordered by a pharmacy can be affected by the type of pharmacy, what it focuses on?

A. The amount of controlled substances could be affected by the type of pharmacy, yes.

Q. And the amount of controlled substances, would you agree is affected as to whether or not the pharmacy that's putting in an order is a specialty pharmacy or a specialized pain management pharmacy versus a normal, typical pharmacy?

A. It could be, yes.

(Continued on next page)

Q. You talked about dispensing data from customers. Now does the -- DA, withdrawn.

Are distributors authorized to demand and receive dispensing data from a pharmacy?

MS. ROTHMAN: Objection.

THE COURT: Overruled. You can answer.

A. Distributors are authorized to obtain dispensing records from their customers, absolutely.

Q. And are those customers obligated under the law to provide dispensing data?

MS. ROTHMAN: Objection, your Honor.

THE COURT: Overruled. You can answer.

A. So the distributors are required to maintain effective

controls of diversion, and part of that would be to look at the prescribing patterns and the dispensing records of the pharmacy. So if the pharmacy refuses to provide that information, the distributor likely should terminate their business with that customer.

Q. You would agree, though, that a pharmacy may have certain reasons that the dispensing data is not being turned over that have nothing to do with it being a suspicious order, correct?

MS. ROTHMAN: Calls for speculation.

THE COURT: Overruled. You can answer.

A. No, I don't think there is any reason they should turn offer the dispensing data to the wholesale distributor, no.

Q. In those cases where the pharmacy turns over dispensing data, would you agree that the data that's turned over by, let's say, a dirty pharmacist will or can include false information?

A. Well, any data that the pharmacy turns over could be false, that's why it's incumbent upon the distributor to corroborate the information that it's provided.

Q. We're going to get to that. I simply asked a question. We're trying to move this.

Is it fair to say that the data that a distributor receives from a pharmacist could be false information?

A. Again, yes.

Q. And it could be false information without the distributor

even knowing it, correct, yes or no?

A. Again, yes. It could be false information.

Q. You also talked about another example of a red flag. You said something about 20 percent of controlled substances of the order, but then you said no, no, maybe 15 percent. Do you recall that?

A. I don't recall in those words, but I do recall the discussions, yes.

Q. By the way, is there any statute or regulation that lays out this 20 percent or 15 percent red flag that you talked to this jury about?

A. Again, that's all part of maintaining effective controls which is in the statute.

Q. I'm being very specific now with my question. Yes or no, is there any statute that says anything about, you should look at whether or not it's 20 percent or 15 percent, yes or no?

A. There's nothing written that states those words in the statute.

Q. Now, with regard to notifying the field office of DEA, what statute specifically states when a registrant must contact the DEA with a suspicious order?

A. The regulations state that they must report them upon discovery.

Q. And that's the -- you testified about that on direct and maybe even on cross, that's the only statute that you can refer

to, correct?

I'm sorry. My mistake, your Honor. That was in the guidance letter that was introduced, correct?

A. No, that's a regulation that we looked at right before the break.

Q. And so other than the regulation as the jury heard it or in the guidance letters, government exhibits that were received in evidence, is it fair to say that there is no specific timeframe that is mentioned in any statute?

A. In that regulation it says upon discovery. Is that your question?

Q. And that's it, correct, ma'am? That's it, correct?

A. Yes.

Q. Now, you talked about compliance programs that must be set up. Can we agree that the DEA has made it clear that there's more than one way to design and operate a system that can identify and report suspicious orders, yes or no?

A. The DEA has stated that it's up to the registrant to design its own system, yes.

Q. The question is, is it fair to say that as a result of that, you would agree that there are many ways, different ways to design and operate a compliance system, correct?

A. Yes, it's up to the registrant to make.

Q. We'll get to that. We're going to get to that.

MS. ROTHMAN: Your Honor, could the witness finish her

answer.

THE COURT: Overruled. Can you redirect.

Mr. Gottlieb move on.

Q. Would you in a compliance program there's no single feature of a suspicious order monitoring program that makes the program compliant with the Controlled Substances Act?

A. Well, what makes it compliant is that it's maintains effective controls against diversion. So if it's not maintaining effective control against diversion, it's not compliant.

Q. Ms. Carter, let me try again. Would you agree that there's no single feature of a suspicious order monitoring program that makes the program compliant with the Controlled Substances Act, yes or no?

A. No. I mean, that's not a yes or no question because the feature, it has to maintain effective controls against diversion.

MR. GOTTLIEB: Your Honor, may I have one moment, please.

THE COURT: Yes.

Q. Do you recall testifying under oath in a civil lawsuit?

A. Yes, I do.

Q. In the *State of New Hampshire v. Johnson & Johnson* on May 18, 2021, do you recall being asked this question?

MS. ROTHMAN: Objection.

THE COURT: Your objection?

MS. ROTHMAN: Hearsay, relevance.

MR. GOTTLIEB: It's a prior inconsistent statement.

THE COURT: Overruled.

MS. ROTHMAN: Your Honor, there has to be a process to try to do a prior inconsistent statement, and I do not believe Mr. Gottlieb has followed that.

THE COURT: Overruled. She can answer.

Q. Do you recall being asked this question and giving this answer in May of 2021.

Question: And you also agree that there's no single feature of a suspicious order monitoring program that makes the program compliant with the CSA?

The Witness, that's you. I would agree that there's not one single feature that makes a system compliant, yes. Were you asked that question and did you give that answer?

A. I would need to see the transcript to know. I mean, there's obviously questions before and after that that probably relate to this question.

But what I just answered, that answer could be correct, but the single feature, the feature that I've said is accurate, that they have to maintain effective controls against diversion. That's what the system requires. If that's not done, then the system is not adequate.

MS. ROTHMAN: Your Honor, could I ask is there a

document number you're reading from?

MR. GOTTLIEB: Defense L5. Would you like to see it?

THE COURT: What's your question.

Q. What I just read to you, would you agree that you were asked that question and you gave that answer, correct? Yes or no?

A. Again, can you tell me where this question is. I don't see it on what was just published.

Q. Can we put it on the board. Defense Exhibit L5, page 125. L5, page 125. Do you see it, ma'am?

A. Not yet. Okay. We are at 125.

Q. Can you just take a look, beginning at line 5 going down to line 11.

Does that refresh your recollection that that was asked of you and that was your answer?

A. That was the answer. I was reading further down where I explained that answer as I just explained it to you.

Q. Would agree that there's no uniform set of rules applied by the DEA as to what makes a suspicious order monitoring program correct, yes or no?

A. Again, the system has to have the outcome of maintaining effective controls against diversion.

Q. Ms. Carter, do you recall testifying on that same day in that same deposition in that civil case in the same case being asked this question and giving this answer, and this is on page

126.

Question: All right. And there's no uniform set of rules applied by DEA as to what makes a suspicious order monitoring program, correct? Right?

Answer: There's no set of rules. Can you define what you mean by that.

Question: Right. There's no checklist at the DEA as to what a suspicious order monitoring system must have in order to be compliant, correct?

Answer: Well, to my knowledge there's no checklist. There wasn't when I left the DEA.

Were you asked those questions and did you give those answers?

MS. ROTHMAN: Objection, your Honor.

THE COURT: Overruled.

A. Yes. And as I -- you did read it correctly, but you're misstating what this says. You're misrepresenting what this says. I asked her to rephrase that question because I didn't understand the question. And then when she asked if there was a check list, I said there is no checklist and there isn't a checklist.

Q. The question that I asked you, were you asked those questions and did you give those answers, yes or no?

A. No. I said, can you define what you mean by that. That's what I said.

MR. GOTTLIEB: Your Honor, can I please have this then on the board, Defendant's L5, page 126.

Q. Do you see it there? Do you have it?

A. I have it.

Q. If you can just look at line 3 through line 12. All I'm asking, were you asked those questions? Did you give those answers. Yes or no?

MR. GOTTLIEB: Your Honor, please, I know we want to get through this. Could you just answer it.

A. Yes, I did say there was no checklist. And if you didn't ask me that now, if you ask me if there's a checklist, I will tell you there's not a checklist.

Q. And I believe you said on direct examination that the DEA does not approve -- does not endorse any specific program for identifying and reporting suspicious orders, correct?

A. The DEA does not approve the systems. That is correct.

Q. And there's no law under the federal criminal statutes that sets forth how DEA registrants must perform a suspicious order monitoring program; is that correct?

MS. ROTHMAN: Objection, your Honor.

THE COURT: Overruled. You can answer.

A. Can you repeat that question.

Q. There is no law or even a regulation that sets forth how DEA registrants must perform suspicious order monitoring, correct?

A. What the regulation states is that they have to design a system that discloses to the registrant suspicious orders of controlled substances.

Q. And that's it, correct?

A. And in doing that, all of that still goes back to their system, it has to maintain effective controls against diversion.

Q. If a registrant such as a distributor reached out to the DEA for guidance on whether a particular order is suspicious, can we agree that the DEA does not provide guidance to the registrant on whether a particular order is suspicious, yes or no?

A. The DEA will not say whether an order is suspicious, but the DEA does provide guidance, so there's two pieces to that question.

Q. They would not tell the distributor whether or not a particular order is suspicious, correct?

A. No, the DEA leaves that for the registrant to make that determination.

Q. If the registrant contacted the DEA, the distributor and asked about a particular order size or frequency, would you agree the DEA would refuse to tell the distributor whether or not that's a suspicious order, correct?

A. Refuse to tell is not really accurate. They would advise the registrant -- the DEA would advise the registrant that they

have to make that determination.

Q. Would you agree that distributors are not qualified to determine whether a prescription on its face has a legitimate medical need?

MS. ROTHMAN: Objection.

THE COURT: Overruled. You can answer.

A. Yeah, I don't think the distributors -- I don't believe that the distributors -- the DEA ever told the distributors that they're supposed to determine a legitimate medical need.

Q. And, in fact, the question was, would you agree that distributors are not qualified to determine whether a prescription on its face has legitimate medical need, yes or no?

A. Again, I don't know. I mean for me to say whether a distributor has that qualification, I can't answer that. I would have to have the facts about that distributor and the people that we're talking about because there may be people working for that distributor that do have that ability to know whether the description for a legitimate medical need.

Q. Would you agree that it is the prescribers who are responsible for determining medical needs when they write prescriptions for opioids, yes or no?

A. Yes.

Q. I think we can all agree that doctors are only supposed to write prescriptions for opioids if they have a doctor patient

relationship and they make an honest judgment about medical needs, correct? You would agree with that?

A. I agree they need to have a valid patient relationship and there needs to be a legitimate medical need, yes.

Q. And you would agree that a distributor does not have any statutory obligation to go out and to determine whether or not the prescription on its face has been demonstrated as for a legitimate medical need?

A. And again, the distributor -- the distributor does not -- no one expects the distributor to make a determination based on the face of the prescription whether there's a legitimate medical need.

Q. What is a PMP? What does that stand for?

A. In some states it stands for prescription monitoring program.

Q. And do you agree that distributors don't have access to PMPs, these monitoring programs?

A. Yes.

Q. Is this a computerized database that the distributors don't even have access to?

A. It is computerized and it's typically run by the state and the distributors don't have access to it.

Q. Because the DEA leaves it up to each registrant to design a suspicious order monitoring system, is it fair to say that the DEA has recognized that a registrant can and should consider a

number of factors before deciding what, if anything, to be done in the face of a red flag?

A. Yeah, a distributor should be reviewing the red flags and making a decision whether or not the red flag can be resolved, yes.

Q. Can we agree that there are recommendations on a number of factors that a distributor or a registrant might consider in evaluating a red flag, correct?

A. Yes, they should be considering all -- they should be using all available resources that they have to look at the orders and determine whether or not they can resolve the red flags.

Q. So a red flag somehow comes to the attention of a distributor, is it fair to say that before the distributor does anything with that red flag, would you agree that some of the factors that may be investigated is the nature of the product, the controlled substance itself, correct?

A. Yes.

Q. The characteristics of the customer, who the customer is, correct?

A. Are you asking if these are things they should consider?

Q. Are those factors that should or can be considered, yes?

A. Yes, they should consider the customer, yes.

Q. And assuming there is a red flag that comes to the attention of a distributor, would you agree that included in what the distributor can do as part of this investigation is to

speak to the customer directly?

A. Yes, they can speak -- they can speak to the customer directly.

Q. And when they speak it's for the purpose of trying to find out what's going on, tell us something about this order, correct?

A. Yes, they should ask the customer what's going on with this order.

Q. And would you agree that in speaking to the customer, in doing your due diligence, the distributor is relying on the customer giving honest answers, correct?

A. Not necessarily. I mean, the distributor should take the answers, but then the distributor should corroborate the answers.

Q. Now, you just mentioned corroboration. First, you would agree that manufacturers and distributors often do rely on what the customer tells them, correct?

A. Yes, they do rely on what the customer tells them, but they should corroborate that information.

Q. Well, regarding corroboration, is it fair to say that while corroboration is recommended, the Controlled Substances Act does not require corroboration?

MS. ROTHMAN: Objection, your Honor.

THE COURT: Overruled. You can answer.

A. So the Controlled Substances Act requires the distributor

to maintain effective controls against diversion. All of that corroboration would be included in the conduct of the due diligence for sure.

Q. If we could get a yes or no answer. While corroboration may be recommended, yes or no, the Controlled Substances Act does not require corroboration, yes or no?

A. The Controlled Substances Act requires that they maintain effective controlled substances against diversion. That's what it requires.

Q. So that the record is clear, I don't want to spend anymore time on it. Your answer is, no, the Controlled Substances Act does not require corroboration?

A. No, it's not really no because part of maintaining effective controlled substance controls against diversion includes corroborated information that you're given by your customers.

MR. GOTTLIEB: May I have Defense exhibit 5L, 139, 140.

Q. Do you recall being asked these questions and giving these answers at the deposition on May 18, 2021.

Question, line 20 on the bottom of 139.

Question: And so no statute or regulation relating to the Controlled Substances Act requires specifically that registrants obtain corroboration of what their customer tells them is the explanation for potentially suspicious order,

correct?

Answer: Well, what the Controlled Substances Act requires is that the registrants maintain effective control against diversion. And again, that's not delineated, like verbatim or in writing. Each company sets up its own system. And part of the effective system would include corroborating what your customer tells you.

Question: And that's the last part, Ms. Carter, that I want to ask you about. Where is it written down anywhere, the part an effective system would include corroborating what your customers tell you?

The witness again. It's not written down. as I said at least three times now because the CSA in implementing regulations do not delineate in writing what a specific company suspicious order monitoring system is going to entail. Each company has to make their own system based on their own business practices, etc., as we discussed already. And part of having and maintaining effective controls against diversion, which is part of it, would be corroborating what your customers tell you.

Were you asked those questions and did you give those answers. Yes or no?

MS. ROTHMAN: Is there a line cite I'm sorry, Mr. Gottlieb.

MR. GOTTLIEB: It was page 139, beginning line 20 on

to the next page.

A. Am I supposed to answer this? Yes.

Q. That's an answer?

A. I did say this and I said exactly what I've been telling you that they're required to maintain effective controls against diversion.

Q. Now, with regard to a compliance program as part of the due diligence, is it fair to say that using former DEA agents as consultants to conduct the investigation of a red flag, is that something that's recognized as recommended?

A. I think each company has to make their own decision whether or not that they would like to use prior DEA employees. I think that it would depend upon the prior DEA employee's experience.

Q. And you would agree that based on your lengthy experience and detailed experience in this field, registrants often use outside consultants to assist them in investigations, correct?

A. Based on my knowledge, yes, they do use them.

Q. Thank you. Now, another factor that I believe you mentioned to know about or to investigate might be the company's history with the customer, correct?

A. Yes.

Q. And the history means how long the company and the registrant, the distributor, might know one another, correct?

A. Well, I would define it as the business relationship.

Q. And history also includes prior investigations of the company that requested the order of controlled substance. Is it fair to say that another area of investigations would properly be prior investigations that were conducted of that company?

A. Prior investigations by whom, by the company?

Q. Let's start with the DEA. Prior investigations by the DEA of the company and its compliance program, would that be a factor that might be investigated?

A. I don't know why that would be investigated. I don't understand. Maybe I'm not understanding you, but I don't know why that would need to be investigated as to why -- as to the DEA investigation.

Q. Let's say you have a pharmacy ABC and the DEA investigated that pharmacy and its compliance program and practices and reported in writing that that pharmacy is compliant, wouldn't that be an important part of the investigation?

A. The DEA doesn't make its investigations public and they don't tell anyone in writing that someone's compliant. That's not how the DEA operates, so I don't know when that would have happened.

Q. Does the DEA prepare investigative reports in writing concerning its activities, yes or no?

A. The DEA does prepare reports of investigation, yes, but those are not public.

Q. And what about internal investigations by the registrant of the pharmacy in question, is that part of a compliance program that is recommended to review?

A. Yes, it should be part of a compliance program. They should be conducting investigations documenting all of those investigations and then using those investigations for future encounters.

Q. Would you agree that if a distributor fails to adequately enforce its own compliance program in detail, it does not necessarily mean that anyone, including the distributor, knows that their customers are diverting controlled substances?

MS. ROTHMAN: Objection to form.

THE COURT: Overruled. You can answer the question if you understand.

A. So if I understand -- just to clarify, are you asking me that even if the distributor doesn't follow its own policies and procedures, that doesn't mean diversion occurred? Was that what you're asking me?

Q. Even if they don't follow all of their procedures, it does not in and of itself mean that the distributor knows that the controlled substances are being diverted?

A. Yeah, even if they don't follow their policy and procedures, it doesn't mean that, but the whole purpose of the --

MR. GOTTLIEB: Your Honor, I didn't ask for the

purpose. We've heard that many times. I'm trying to move this. May I continue.

THE COURT: Please.

MR. GOTTLIEB: Thank you.

Q. Based on your experience and your expertise in this area, must every registrant report every suspicious order to the DEA?

A. Yes, every suspicious order should be reported to the DEA upon discovery.

Q. If there is a red flag brought to the attention of a distributor, are you saying that the distributor must immediately contact the DEA?

A. No, if a red flag has been brought to the attention of the distributor, that is not in and of itself a suspicious order. It's a red flag.

Q. And the reason why that is, would you agree that the DEA has taken the position that it would be pointless and worthless to report every red flag because there's simply not the time and resources to investigate each of those red flags, correct?

A. I don't know if the DEA said don't report all red flags. They may have. I just don't recall that right now.

Q. Did you meet with the government on January 13, 2022? Do you recall meeting with prosecutors on that day?

A. I met with -- who did I meet with? I don't recall what you're talking about.

Q. The prosecutors in this courtroom, Ms. Rothman?

A. On the 13th of January?

Q. January 13, 2022, yes.

A. I may have had a conference video chat, but I didn't meet with them. I don't recall the dates that I talk to prosecutors in this case, no.

Q. Do you recall being asked questions about distributors printing reports and sending them to the DEA. Do you recall that conversation along those lines?

A. Are you talking about this morning when I was asked questions about the prosecutor? Is that what you're referring to or a meeting I met with them?

Q. January 13, 2022.

A. I don't even know today's date. Could you tell me today's date.

Q. Do all companies in your experience report every flagged order, yes or no?

A. No, the companies are not required to report every flagged order.

Q. Would it be helpful to the DEA in performing its duties to have every registrant report every flagged order of potentially suspicious orders, yes or no?

A. The flagged orders -- they're required to report suspicious orders. There's nothing that discusses reporting flagged orders.

Q. My question, ma'am, would it be helpful to the DEA to have

every flagged order sent to them for the DEA to perform its duties? Would it be helpful, yes or no?

A. I'm not authorized to speak on behalf of the DEA, so I, as far as that goes, I don't know.

MR. GOTTLIEB: Can we have Defendant's L5 again, 135. Your Honor, if I could have one moment.

Q. Do you recall being asked this question and giving this answer. Page 135 in that same deposition under oath.

Question, starting at line 16. Okay. And it wouldn't be helpful to DEA for registrants to be reporting every flagged or potentially suspicious order to the local field office, correct?

Answer: Well, it would not be helpful to report every flagged order. It also would not be what the regulations require.

Do you recall being asked that question and giving that answer?

A. I do, but I also have been since advised by DOJ attorneys that I'm not authorized to speak on behalf of DEA. So whether it's helpful to DEA, that's not for me to say. So I should not have said this is kind of what I was told.

But, it is not what the regulation requires. The regulations require that the suspicious orders be reported. That's what the regulation requires.

Q. And some DEA attorney told you that you should not have

answered that question?

MS. ROTHMAN: Objection, your Honor.

THE COURT: Sustained.

Q. If an order is flagged, Ms. Carter, do you agree that you're not aware of any company that literally just stops and has stopped shipments of all orders that are flagged, are you aware of that?

A. Are you asking me if I'm aware if there's any company that stops all shipments of flagged orders?

Q. Are you aware that there are companies that even after an order is flagged, that they literally just stop shipments of all orders that are flagged. Are you aware of that?

A. If you're going back to that New Hampshire deposition, I believe the attorney was referring to prior to 2007. I believe that's what he was referring to. I'm having to be careful how I'm answering. You're making it out like I'm not being truthful and that's not truthful.

Q. Put it on the board. Defendant's L5, 135, 137. Do you recall being asked these questions and giving these answers in May of 2021, beginning line 7 going down to 22, page 137.

Question: Okay. Well, let me -- withdrawn. You mentioned about some attorney was asking you questions. Just so the record is clear, that's not me, correct?

MS. ROTHMAN: Objection, your Honor.

THE COURT: Overruled.

A. Well, because you keep going back to this deposition. You're mixing it up. You're trying to confuse what I said, and a lot of times what these questions were asked and it wasn't even -- the context wasn't the same as what you're asking me. So I said I believe that that would have been what the attorney was referring to in this deposition about those suspicious orders, those excessive purchase reports, that were being sent. Did any company ever stop all shipments, that's what I believed that you were asking about. If that's what you were asking about, then that was a different context than what you're asking me right now.

Q. Do you recall being asked this question and being -- based on what you told the jury just a few moments ago.

Question: Well, let me ask that question. If all the registrants treated every order that was flagged as though it was a suspicious order and would not ship it, that could have adverse impacts on patients that would have a legitimate medical need for the medications in that order, correct?

The witness: I can't say one way or the other that it would cause an adverse impact, because I don't think that's ever -- I don't think that's ever happened, so you don't know what the -- what the report would look like.

I mean, I don't know of any drug company that literally just stops -- has stopped shipments of all orders that they flagged, so I don't really know what impact that

would have on the public health. I'm not sure.

Were you asked that question and did you give that answer in particular about stopping the shipments, yes or no?

A. That is the question that I was asked and that is the answer that I gave as it's written here, yes.

Q. You told the jury on direct that you've, over the years, you've done a lot of work, investigations, would you also have attended conferences and seminars, correct?

A. Yes.

Q. And you've even taught, correct?

A. I gave presentations, yes.

Q. And at these conferences, at these seminars, is it fair to say that there has been a dialogue among the participants as to whether or not the DEA has been clear to registrants about what a suspicious order is and what to do when you have it, has that been a topic?

MS. ROTHMAN: Objection.

THE COURT: Sustained as to the form of the question.

Q. Do you know Larry Houck?

A. I do not.

Q. H-O-U-C-K?

A. I do not know him, no.

Q. Have you read any of his writings?

A. I have read his writings in depositions, yes.

Q. Your answer now is you have read Larry Houck's writings

regarding whether or not the law is clear enough concerning suspicious orders and what to do; is that correct?

MS. ROTHMAN: Objection, relevance.

THE COURT: I'm going to sustain the objection.

Q. Is Larry Houck a respected, as far as you know, authority in this area of suspicious orders and regulations concerning diversion?

MS. ROTHMAN: Objection.

THE COURT: Sustained.

Q. Do you agree with this statement, The DEA does not provide sufficient guidance for how to conduct due diligence, yes or no?

MS. ROTHMAN: Objection.

THE COURT: Overruled. You can answer.

A. Do I agree that that's accurate, no. I think the DEA does provide information.

Q. I think I said sufficient information and guidance?

A. I do believe that the DEA provides sufficient information guidance.

Q. Do you agree with the following: The lack of a clear standard or understanding of the DEA's expectations for the regulated industry, especially as related to legal and regulatory requirements, is forcing companies to limit, and in some cases make arbitrary distribution or dispensing decisions. Do you agree with that?

A. I would need to see the context of this document. I mean there's -- I would need to see what you're reading from.

Q. Forgot what I'm reading from. Do you agree with what I just asked you, yes or no?

A. Can you say it again.

Q. Do you agree that the lack of a clear standard or understanding of the DEA's expectations for the regulated industry as related to legal and regulatory requirements is forcing companies to limit, and in some cases make arbitrary distribution or dispensing decisions. Do you agree with that?

A. No.

Q. Do you agree that there is any need to improve the guidance concerning the regulations concerning suspicious orders and compliance, yes or no?

MS. ROTHMAN: Objection, your Honor.

THE COURT: Overruled. You can answer.

A. Can you repeat that.

Q. Do you agree that DEA's regulation concerning compliance and suspicious orders should be clarified?

A. I mean, I think that the regulations and guidance are very clear, so I don't -- I know that there's been a new -- I believe the regulations and guidance have been very clear.

Q. Do you agree that the DEA has failed to sufficiently establish a clear understanding of what is expected of a distributor when investigating a flagged order, yes or no?

A. Do I agree that the DEA has not provided clear guidance into --

Q. Sufficient clear guidance, correct?

A. I don't agree with that, no.

Q. In any of these conferences that you have attended, the seminars, has that issue been a topic of conversation?

MS. ROTHMAN: Objection, your Honor.

THE COURT: Sustained.

Q. Have you ever commented before today's testimony in this courtroom as to whether or not there's a need for increased clarification of the rules and regulations?

A. I think that any time I've been asked that I've said that I believe that regulations are clear.

Q. Would you agree that the suspicious order regulation broadly and somewhat vaguely defines suspicious orders?

A. No, I think the regulations clear.

Q. And you were asked on direct examination about those two guidance letters to registrants, they are from 2006 and 2007, correct?

A. Yes.

Q. You'd agree that without going over the letters again and what's in it, the two formed letters stated generally what a suspicious order may look like and what a distributor may do to detect such orders, correct?

A. Well, they're not form letters. They were letters, the

same letters sent to everyone, and I do believe that it did give specific guidance, yes, regarding suspicious orders and maintaining effective controls against diversion.

Q. Is it fair to say -- would you agree that the DEA has concluded in the letters by warning that distributors should consider the totality of the circumstances when evaluating an order for controlled substance, just as the DEA will do when determining whether the filing of an order with the public's interest is within the meaning of the law?

A. Yeah, I agree that that's generally what the letter said, yes.

Q. Would you agree that the letters that the government introduced did not provide any substantive guidance about what distinguishes a legitimate order from a suspicious one and therefore unfillable and reportable order?

MS. ROTHMAN: Objection to form.

THE COURT: Overruled. You can answer if you understand.

A. I believe the letter did provide clear guidance or the letters.

Q. In that 2007 letter it indicated, and would you agree, that the letter explained that whether an order is also suspicious depends on the ordering patterns of the customer, the patterns of the distributor's customer base and on patterns throughout the relevant segment of the regulated industry? Do you agree

with that?

A. Can you repeat the first part of that question again.

Q. Do you agree that the letter explained that whether an order is also suspicious depends on the ordering pattern of the customer, on the patterns of the distributor customer base and on patterns throughout the relevant segment of the regulated industry?

A. Yeah, I mean, those are things to consider, and I believe that the letter said that, but I would need to go to the letter. I don't know which letter said it. There were two.

Q. At these conferences, you would agree that despite efforts made by the DEA to do its job, would you agree that you have heard more than once that distributors continue to lack confidence that they are complying with what DEA expects, especially given the lack of regulatory guidance?

MS. ROTHMAN: Objection, hearsay.

THE COURT: Sustained.

MR. GOTTLIEB: Your Honor, I'm just about done.

Q. Would you agree that there would be a benefit to DEA registrants for there to be a more specific delineation of what a suspicious order is and what to do each step along the way to report it, would there be some benefit to registrants to have that done?

MS. ROTHMAN: Objection.

THE COURT: Overruled. You can answer.

A. I think that with all of the different types of businesses and the different business practices of each registrant, there's not really one. There's not really a way to write out a road map for the distributors. The distributors are required to maintain effective control against diversion, and there's no way to make a complete list. Because one thing about this, the drug abuse problems and the drugs, the situation with the drugs in this country and the reason these substances are classified as controlled substances is they're very dangerous.

And things change, so patterns change. And then what you'll find, what happens with people is they abuse drugs or people that are doing the nefarious things, they change their patterns. So if the DEA were to put out a list, this is what you're to do, then they'll just change their patterns. And another thing, the list, the DEA doesn't put out a list.

MR. GOTTLIEB: Your Honor, thank you very much.

THE COURT: Did you want to adjourn for the day or did you want to try to wind up with her quickly?

MS. ROTHMAN: Your Honor, it's five o'clock. I'm happy to proceed with redirect in the interest of not having to --

THE COURT: Only if you have five minutes worth of redirect.

MS. ROTHMAN: It's a little more than five minutes. I defer to the Court as to how your Honor would like to proceed.

I can try to go quickly as possible.

THE COURT: If you can finish up in five to seven minutes. If you can't finish up in that time, we should come back.

MS. ROTHMAN: I'll try my best. Thank you, your Honor.

REDIRECT EXAMINATION

BY MS. ROTHMAN:

Q. Good afternoon, Ms. Carter.

A. Good afternoon.

Q. Do you recall being asked questions on cross examination about the guidance that the DEA provides to distributors?

A. Yes.

Q. Why doesn't the DEA tell distributors exactly what their suspicious order monitoring system needs to look like?

A. Because each business is different and each -- only the registrant is the one that knows its customers or the distributors is the one that knows its customers. The DEA doesn't know the customers. The DEA doesn't send sale reps into the company or into the customer every week or every other week. The DEA doesn't know the ordering patterns of the customer.

Q. Do you recall being asked questions about the guidance that the DEA may or may not give with respect to whether a particular order is suspicious?

A. Do you --
Q. Do you recall guidance that the DEA may give with respect to whether a particular order is suspicious?
A. Are you referring to as far as in these letters or just the guidance in general?
Q. On cross examination --
A. Yes.
Q. If a distributor doesn't investigate flagged orders, are they maintaining effective controls against diversion?
A. No.
Q. If a distributor starts selling controlled substances to a customer without doing any due diligence --
MR. GOTTLIEB: Your Honor, objection. May we please have a sidebar.
THE COURT: I'm going to sustain as to the form of the question. You want to attempt to restate the question.
Q. Ms. Cater, do you recall being asked questions about the guidance that the DEA provides to distributors on cross examination?
A. Yes.
Q. Is a fact that a customer is a particularly large customer a reason not to report a suspicious order?
A. No. If the order is suspicious, the order should be reported. If they determine the order is suspicious, it's required to be reported.

Q. Is the fact that a customer is a board member of a distributor a reason not to report a suspicious order?

MR. GOTTLIEB: Objection.

THE COURT: I'll allow her to answer that, but I think this is going beyond cross. You can answer.

A. No, that doesn't matter. Because if the order is suspicious, it needs to be reported.

Q. Do you recall being asked questions on cross examination about red flags of diversion and also flagged orders?

A. Yes.

Q. I want to take those piece by piece. What is, generally speaking, a red flag of diversion?

A. So the regular flag is the warning sign, so it's just a warning sign that this pattern or this behavior could indicate potential diversion.

Q. What is a distributor supposed to do when they see or learn of red flags of diversion?

A. When they see red flags with an order, they need to investigate that to determine if there's actually some truth to those red flags. Or if they cannot dispel the red flags or resolve the red flags, then they shouldn't ship the order.

Q. With respect to a flagged order in a suspicious order monitoring system, how is that different than -- withdrawn.

What is a distributor supposed to do when they see a flagged order and a suspicious order monitoring system?

A. Well, the flagged orders are typically the distributors way of marking -- flagging, for lack of a better term, that you're flagging the order; but it must meet some type of criteria that they the distributor determined that they would use to flag the order. It's not a suspicious order in and of itself. It's a flagged order, and they must then review that order and determine whether or not that order is indeed suspicious.

Q. Do you recall being asked questions on cross examination about distributors having DEA agents on staff?

A. Yes.

Q. Does having a DEA agent on staff mean that a distributor has an effective system to maintain effective control against diversion?

A. No, it does not.

Q. Why not?

A. Well, because, again, it depends on the experience of the prior DEA employee. It has to be taken into consideration. And just because the DEA or the person worked at the DEA in the past, doesn't mean that the system is effective or that they're following the law and the regulations.

(Continued on next page)

Q. Do you recall being asked questions about whether or not a distributor can see if a prescription on its face is illegitimate?

A. Yes.

Q. What is a distributor supposed to do before shipping to a pharmacy any controlled substance?

A. They're supposed to determine if the orders are legitimate, and if they're not legitimate, they should not ship the orders.

Q. Ms. Carter, do you recall being asked questions about the DEA letters that were sent to Rochester Drug Co-Operative in 2006 and 2007 on cross-examination?

A. Yes.

Q. If we can pull up Government Exhibit 273, please, for the witness. If we can zoom in on the first paragraph. I'm sorry, the second paragraph. Thank you, Ms. Drescher.

I am going to ask you to read the first sentence, Ms. Carter.

A. "In addition to, and not in lieu of, the general requirement under 21 U.S.C. 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances."

Q. Do these letters clearly tell distributors what their obligations are under the law?

MR. GOTTLIEB: I am going to object to "clearly."

THE COURT: Sustain the objection as to the form of the question.

Q. Do these letters tell distributors what their obligations are under the law?

A. Yes, they absolutely do.

MS. ROTHMAN: May I have one moment?

THE COURT: Yes.

MS. ROTHMAN: I have no further questions.

THE COURT: Do you have anything further, Mr. Gottlieb?

MR. GOTTLIEB: No, your Honor. Thank you.

THE COURT: We'll excuse this witness.

(Witness excused)

THE COURT: Ladies and gentlemen, I want to keep us on schedule. I think we are on schedule, and I am still trying to get us ahead of schedule.

Don't discuss the case, keep an open mind. I'll ask you to be inside the jury room at 9:45 and we'll see how much we can get done tomorrow.

(Jury excused)

THE COURT: Let's prepare to move forward with the next witness at 9:45 tomorrow. I'll see everybody tomorrow at 9:30.

MS. ROTHMAN: Thank you, your Honor.

(Adjourned until January 19, 2022, at 9:30 a.m.)

INDEX OF EXAMINATION

GOVERNMENT EXHIBITS

DEFENDANT EXHIBITS